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9:00 a.m.–Noon

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Washington, DC 20002

RESERVATIONS: (202) 741–6008

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Tuesday, May 1, 2007

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 982

[Docket No. AMS–FV–06–0175; FV07–982–1 FIR]

Hazelnuts Grown in Oregon and Washington; Establishment of Final Free and Restricted Percentages for the 2006–2007 Marketing Year

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: The Department of Agriculture (USDA) is adopting, as a final rule, an interim final rule establishing final free and restricted percentages for domestic inshell hazelnuts for the 2006–2007 marketing year under the Federal marketing order for hazelnuts grown in Oregon and Washington. This rule continues in effect the final free and restricted percentages of 8.2840 percent and 91.7160 percent, respectively. The percentages allocate the quantity of domestically produced hazelnuts which may be marketed in the domestic inshell market (free) and the quantity of domestically produced hazelnuts that must be disposed of in outlets approved by the Board (restricted). Volume regulation is intended to stabilize the supply of domestic inshell hazelnuts to meet the limited domestic demand for such hazelnuts with the goal of providing producers with reasonable returns. This rule was recommended unanimously by the Hazelnut Marketing Board (Board), which is the agency responsible for local administration of the marketing order.

DATES: *Effective:* May 31, 2007 the regulation published January 22, 2007 (72 FR 2599, Jan. 22, 2007) is confirmed as final. This rule applies to all 2006–2007 marketing year restricted hazelnuts until they are properly disposed of in accordance with marketing order requirements.

FOR FURTHER INFORMATION CONTACT: Barry Broadbent or Gary Olson, Northwest Marketing Field Office, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1220 SW Third Avenue, Suite 385, Portland, OR 97204; Telephone: (503) 326–2724, Fax: (503) 326–7440, or e-mail: *Barry.Broadbent@usda.gov* or *GaryD.Olson@usda.gov*.

Small businesses may request information on complying with this regulation by contacting Jay Guerber, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or e-mail: *Jay.Guerber@usda.gov*.

SUPPLEMENTARY INFORMATION: This rule is issued under Marketing Agreement No. 115 and Marketing Order No. 982, both as amended (7 CFR part 982), regulating the handling of hazelnuts grown in Oregon and Washington, hereinafter referred to as the ''order.'' The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.''

USDA is issuing this rule in conformance with Executive Order 12866.

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is intended that this action apply to all merchantable hazelnuts handled during the 2006–2007 marketing year beginning July 1, 2006. This action applies to all 2006–2007 marketing year restricted hazelnuts until they are properly disposed of in accordance with marketing order requirements. This rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This rule continues in effect free and restricted percentages which allocate the quantity of domestically produced hazelnuts which may be marketed in domestic inshell markets (free) and hazelnuts which must be exported, shelled, or otherwise disposed of by handlers (restricted). The Board met and, after determining that volume regulation would tend to effectuate the declared policy of the Act, developed a marketing policy to be employed for the duration of the 2006–2007 marketing year. Volume regulation is intended to stabilize the supply of domestic inshell hazelnuts to meet the limited domestic demand for such hazelnuts with the goal of providing producers with reasonable returns. Based on an estimate of the domestic inshell trade demand and total supply of domestically produced hazelnuts available for the 2006–2007 marketing year, the Board voted unanimously at their November 15, 2006, meeting to recommend to USDA that the final free and restricted percentages for the 2006–2007 marketing year be established at 8.2840 percent and 91.7160 percent, respectively.

The Board's authority to recommend volume regulation and use computations to determine the allocation of hazelnuts to individual markets is specified in § 982.40 of the order. Under the order's provisions, free and restricted market allocations of hazelnuts are expressed as percentages of the total hazelnut supply subject to regulation. The percentages are derived by dividing the estimated domestic inshell trade demand (computed by formula) by the Board's estimate of the total domestically produced supply of hazelnuts that are expected to be available over the course of the marketing year.

Inshell trade demand, the key component of the marketing policy, is

the estimated quantity of inshell hazelnuts necessary to adequately supply the domestic inshell hazelnut market for the duration of the marketing year. The Board determines the domestic inshell trade demand for each year and uses that estimate as the basis for setting the percentage of the available supply of domestically produced hazelnuts that handlers may ship to the domestic inshell market throughout the marketing season. The order specifies that inshell trade demand be computed by averaging the preceding three years' trade acquisitions of inshell hazelnuts, allowing adjustments for abnormal crop or marketing conditions. In addition, the Board may increase the computed inshell trade demand by up to 25 percent, if market conditions warrant an increase.

As required by the order, prior to September 20 of each marketing year, the Board meets to establish its marketing policy for that year. If the Board determines that volume control would tend to effectuate the declared policy of the Act, the Board then follows a procedure, specified by the order, to compute and announce preliminary free and restricted percentages. The preliminary free percentage releases 80 percent of the adjusted inshell trade demand that handlers may ship to the domestic market. The purpose of releasing only 80 percent of the inshell trade demand under the preliminary stage of regulation is to guard against any potential underestimate of crop size. The preliminary free percentage is expressed as a percentage of the total hazelnut supply subject to regulation, where total supply is the sum of the estimated crop production less the three-year average disappearance plus the undeclared carry-in from the previous marketing year.

On August 22, 2006, the National Agricultural Statistics Service (NASS) released an estimate of 2006 hazelnut production for the Oregon and Washington area at 41,000 dry orchard-run tons. NASS uses an objective yield survey method to estimate hazelnut production which has historically been very accurate.

On August 24, 2006, the Board met for the purpose of (1) Determining if volume control regulation would tend to effectuate the declared policy of the Act; (2) estimating the total available supply and the domestic inshell trade demand for hazelnuts; (3) establishing preliminary free and restricted marketing percentages for the 2006–2007 marketing year; and (4) authorizing market outlets for restricted hazelnuts.

After discussion, the Board unanimously determined that volume regulation is necessary to effectively market the industry's 2006 crop and would tend to effectuate the declared policy of the Act. The determination was based on (1) The large size of the 2006 hazelnut crop; (2) the inability of the domestic inshell market to absorb such a large crop; (3) the projected record-setting world hazelnut crop and the probability of an oversupplied world market; and (4) the average price paid to Oregon-Washington growers has not exceeded the parity price in any one of the past 18 years.

The Board then estimated the total available supply for the 2006 crop year to be 39,234 tons. The Board arrived at that quantity by using the crop estimate compiled by NASS (41,000 tons) and then adjusting that estimate to account for disappearance and carry-in. The order requires the Board to reduce the crop estimate by the average disappearance over the preceding three years (1,792 tons) and to increase it by the amount of undeclared carry-in from previous years' production (26 tons).

In the calculation, disappearance is defined as the difference between the estimated orchard-run production and the actual supply of merchantable product available for sale by handlers. Disappearance can consist of (1) Unharvested hazelnuts; (2) culled product (nuts that are delivered to handlers but later discarded); (3) product used on the farm, sold locally, or otherwise disposed of by producers; and (4) statistical error in the orchard-run production estimate.

Undeclared carry-in is defined as hazelnuts that were produced in a previous marketing year but were not subject to regulation because they were not shipped during that marketing year. Undeclared carry-in is subject to regulation during the current marketing year and is accounted for as such by the Board.

Additionally, the Board estimated domestic inshell trade demand for the 2006–2007 marketing year to be 3,067 tons. The Board arrived at this estimate by taking the average of the domestic inshell trade acquisitions for the 2002–2005 marketing years (2,775 tons) and then reducing that quantity by the declared carry-in from last year's crop (124 tons). The trade acquisition data for the 2005–2006 marketing year was omitted from the Board's calculations, as allowed by the order, after it was determined to be abnormal due to crop and marketing conditions.

The declared carry-in represents product regulated under the order during a preceding marketing year but not shipped during that year. This inventory must be accounted for when estimating the quantity of product to make available to adequately supply the market.

After establishing estimates for total available hazelnut supply and domestic inshell trade demand, the Board used those estimates to compute and announce preliminary free and restricted percentages of 5.4055 percent and 94.5945 percent, respectively. The Board computed the preliminary free percentage by multiplying the adjusted inshell trade demand by 80 percent and dividing the result by the estimate of the total available supply subject to regulation (2,651 tons x 80 percent/39,234 tons = 5.4055 percent). The preliminary free percentage initially released 2,121 tons of hazelnuts from the 2006–2007 supply for domestic inshell use. The Board authorized the preliminary restricted percentage (37,113 tons) to be exported or shelled for the domestic kernel markets.

Under the order, the Board must meet again on or before November 15 to review and revise the preliminary estimate of the total available supply of hazelnuts and to recommend interim final and final free and restricted percentages. Initially, when establishing preliminary free and restricted percentages, the Board utilizes a pre-harvest objective yield survey, compiled by NASS on behalf of the Board, to estimate the upcoming crop size. After the hazelnut harvest has concluded, usually sometime in October, information is available directly from handlers to more accurately estimate crop size. The Board may use this information to amend their preliminary estimate of total available supply before calculating the interim final and final percentages.

Interim final percentages are calculated in the same way as the preliminary percentages but release 100 percent of the inshell trade demand, effectively releasing the additional 20 percent held back at the preliminary stage. Final free and restricted percentages may release up to an additional 15 percent of the average trade acquisitions of inshell hazelnuts for desirable carryout, to provide an adequate carryover of product into the following season. The order requires that final free and restricted percentages be effective 30 days prior to the end of the marketing year, or earlier, if recommended by the Board and approved by USDA. The Board is allowed to combine the interim final and the final stages of the marketing policy, if marketing conditions so warrant, by recommending final

percentages which immediately release 100 percent of the inshell trade demand (the preliminary percentage plus the additional 20 held back) plus any percentage increase the Board determines for desirable carryout. Revisions in the marketing policy can be made until February 15 of each marketing year, but the inshell trade demand can only be revised upward, consistent with § 982.40(e).

The Board met on November 15, 2006, and reviewed and approved an amended marketing policy and recommended the establishment of final free and restricted percentages. During the meeting, the Board revised the crop estimate in the marketing policy to 38,688 tons (from 41,000 tons), which reflects the results of post-harvest handler survey information compiled by the Board. In addition, the Board decided that market conditions were such that the immediate release of an additional 15 percent of the three-year average trade acquisitions to allow for desirable carryout will not adversely affect the 2006–2007 domestic inshell market. Final percentages were recommended at 8.2840 percent free and 91.1760 percent restricted. The final free percentage releases 3,067 tons of inshell hazelnuts from the 2006–2007 supply for domestic use, which includes 416 tons for desirable carryout. Accordingly, since the final percentages were recommended for immediate release, no recommendations for interim final free and restricted percentages were necessary.

The final marketing percentages are based on the Board's final production estimate and the following supply and demand information for the 2006–2007 marketing year:

		Tons
Total available supply:		
(1) Production forecast (11/15/06 crop estimate)		38,688
(2) Minus: Disappearance (three year average—4.37 percent of Item 1)		-1,691
(3) Merchantable production (Item 1 minus Item 2)		36,997
(4) Plus: Undeclared carry-in as of July 1, 2006 (subject to 2006–2007 regulation)		+26
(5) Available supply subject to regulation (Item 3 plus Item 4)		37,023
Inshell Trade Demand:		
(6) Average trade acquisitions of inshell hazelnuts (three prior years domestic sales)		2,775
(7) Plus: Increase to encourage increased sales (15% of average trade acquisitions)		+416
(8) Minus: Declared carry-in as of July 1, 2006 (not subject to 2006–2007 regulation)		-124
(9) Adjusted inshell trade demand (Item 6 plus Item 7 minus Item 8)		3,067
Percentages	Free	Restricted
(10) Final percentages (Item 9 divided by Item 5) x 100	8.2840	91.7160
(11) Final free tonnage (Item 9)	3,067	.....
(12) Final restricted tonnage (Item 5 minus Item 11)	.....	33,956

In addition to complying with the provisions of the order, the Board also considered USDA's 1982 ''Guidelines for Fruit, Vegetable, and Specialty Crop Marketing Orders'' (Guidelines) when making its computations in the marketing policy. This volume control regulation provides a method to collectively limit the supply of inshell hazelnuts available for sale in domestic markets. The Guidelines provide that the domestic inshell market has available a quantity equal to 110 percent of prior years' shipments before allocating supplies for the export inshell, export kernel, and domestic kernel markets. This provides for a plentiful supply of inshell hazelnuts for consumers and for market expansion, while retaining the mechanism for dealing with oversupply situations. The established final percentages make available approximately 416 additional tons to encourage increased sales. The total free supply for the 2006–2007 marketing year is estimated to be 3,067 tons of hazelnuts, which is 127 percent of the average of the last three prior years' sales and exceeds the goal of the Guidelines.

Final Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this final regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

Small agricultural producers are defined by the Small Business Administration (13 CFR 121.201) as those having annual receipts of less than $750,000, and small agricultural service firms are defined as those having annual receipts of less than $6,500,000. There are approximately 700 producers of hazelnuts in the production area and approximately 18 handlers subject to regulation under the order. Using statistics compiled by NASS, the average value of production received by producers in 2004 and 2005 was $57,912,000. Using those estimates, the average annual hazelnut revenue per producer would be approximately $82,700. The level of sales of other crops by hazelnut producers is not known. In addition, based on Board records, about 83 percent of the handlers ship under $6,500,000 worth of hazelnuts on an annual basis. In view of the foregoing, it can be concluded that the majority of hazelnut producers and handlers may be classified as small entities.

Board meetings are widely publicized in advance of the meetings and are held in a location central to the production area. The meetings are open to all industry members and other interested persons who are encouraged to participate in the deliberations and voice their opinions on topics under discussion. Thus, Board recommendations can be considered to represent the interests of small business entities in the industry.

Currently, U.S. hazelnut production is allocated among three main market

outlets: Domestic inshell, export inshell, and kernel markets. Handlers and growers receive the highest return for sales in the domestic inshell market. They receive less for product going to export inshell, and the least for kernels. Based on Board records of average shipments for 1996–2005, the percentage going to each of these markets was 10 percent (domestic inshell), 51 percent (export inshell), and 37 percent (kernels). Other minor market outlets make up the remaining 2 percent.

The inshell hazelnut market can be characterized as having limited and inelastic demand with a very short primary marketing period. On average, 79 percent of domestic inshell hazelnut shipments occur between October 1 and November 30, primarily to supply holiday nut demand. The inshell market is, therefore, prone to oversupply and correspondingly low grower prices in the absence of supply restrictions. This volume control regulation provides a method for the U.S. hazelnut industry to limit the supply of domestic inshell hazelnuts available for sale in the continental U.S. and thereby mitigate market oversupply conditions.

Many years of marketing experience led to the development of the current volume control procedures. These procedures have helped the industry solve its marketing problems by keeping inshell supplies in balance with domestic needs. Volume controls ensure that the domestic inshell market is fully supplied while protecting the market from the negative effects of oversupply.

Although the domestic inshell market is a relatively small portion of total hazelnut sales (averaging 10 percent of total shipments for 1996–2005), it remains a profitable market segment. The volume control provisions of the marketing order are designed to avoid oversupplying this particular market segment, because that would likely lead to substantially lower grower prices. The other market segments, export inshell and kernels, are expected to continue to provide good outlets for U.S. hazelnut production into the future. Adverse climatic conditions that negatively impacted hazelnut production in the other hazelnut producing regions of the world in 2004 and 2005 have corrected and the total world supply in 2006–2007 is predicted to increase dramatically. Product prices in the world market have trended downward in the expectation of the greater supply. While the U.S. hazelnut industry continues to experience high demand for their large sized and high quality product, the prices that producers receive are tied to the global market. In light of the anticipated world oversupply situation, regulation of the domestic inshell market is important to the U.S. hazelnut industry to insulate that specialty market from the supply related challenges of the world hazelnut market.

In Oregon and Washington, high hazelnut production years typically follow low production years (a historically consistent pattern). The 2005 crop of 27,600 tons was 16 percent below the 32,685 ton average for the 1995–2004 period, while the preliminary NASS estimate for 2006 is 25 percent higher. The lowest production (15,000 tons in 1998) and highest production (49,500 tons in 2001) were 47 and 151 percent, respectively, of the 10 year average.

This cyclical trait also leads to an inversely corresponding cyclical price pattern for hazelnuts. Grower price, however, does not fluctuate to the extent of production. The lower level of variability of price versus the variability of production provides an illustration of the order's price-stabilizing impact. The coefficient of variation (a standard statistical measure of variability; ''CV'') for hazelnut production over the most recent 10-year period is 0.36. In contrast, the coefficient of variation for hazelnut grower prices over the same period is 0.19, about half of the CV for production. The lower level of variability of price versus the variability of production provides an illustration of the order's price-stabilizing impact.

Comparing grower revenue to cost is useful in highlighting the impact on growers of recent product and price levels. A recent hazelnut production cost study from Oregon State University estimated cost-of-production per acre to be approximately $1,340 for a typical 100-acre hazelnut enterprise. Average grower revenue per bearing acre (based on NASS acreage and value of production data) equaled or exceeded that typical cost level less than half the time from 1995 to 2004. Average grower revenue was below typical costs in the other years. While crop size has fluctuated, volume regulations contribute to orderly marketing and market stability by moderating the variation in returns for all producers and handlers, both large and small.

While the level of benefits of this rulemaking is difficult to quantify, the stabilizing effects of volume regulation impact both small and large handlers positively by helping them maintain and expand markets even though hazelnut supplies fluctuate widely from season to season. This regulation provides equitable allotment of the most profitable market, the domestic inshell market. That market is available to all handlers, regardless of size.

As an alternative to this regulation, the Board discussed not regulating the marketing of the 2006 hazelnut crop. However, without any regulation in effect, the Board believes that the industry would tend to oversupply the inshell domestic market. The 2006 hazelnut crop is larger than last year's crop and 22 percent above the ten-year average. The unregulated release of 38,688 tons on the domestic inshell market could easily oversupply the small, but lucrative domestic inshell market. The Board believes that any oversupply would completely disrupt the market, causing producer returns to decrease dramatically.

Section 982.40 of the order establishes a procedure and computations for the Board to follow in recommending to USDA establishment of preliminary, interim final, and final percentages of hazelnuts to be released to the free and restricted markets each marketing year. The program results in a plentiful supply of hazelnuts for consumers and for market expansion while retaining the mechanism for dealing with oversupply situations.

Hazelnuts produced under the order comprise virtually all of the hazelnuts produced in the U.S. This production represents, on average, less than 2 percent of total U.S. production of all tree nuts, and less than 7 percent of the world's hazelnut production.

Last season, 85 percent of the domestically produced hazelnut kernels were marketed in the domestic market and 15 percent were exported. Domestically produced kernels generally command a higher price in the domestic market than imported kernels. The industry is continuing its efforts to develop and expand other markets with emphasis on the domestic kernel market. Small business entities, both producers and handlers, benefit from the expansion efforts resulting from this program.

Inshell hazelnuts produced under the order compete well in export markets because of their high quality. Based on Board statistics, Europe has historically been the primary export market for U.S. produced inshell hazelnuts. Shipments have also been relatively consistent, not varying much from the 10 year average of 4,958 tons. Recent years, though, have seen a significant increase in export destinations. Last season, inshell shipments to Europe totaled 4,622 tons, representing just 38 percent of exports, with the largest share going to Germany. Inshell shipments to Southwest Pacific countries, and Hong Kong in particular, have increased dramatically in the past

few years, rising to 50 percent of total exports of 12,042 tons for the 2005–2006 marketing year. The industry continues to pursue export opportunities.

There are some reporting, recordkeeping, and other compliance requirements under the order. The reporting and recordkeeping burdens are necessary for compliance purposes and for developing statistical data for maintenance of the program. The information collection requirements are currently approved by the Office of Management and Budget under OMB No. 0581–0178, Vegetable and Specialty Crops. The forms require information which is readily available from handler records and which can be provided without data processing equipment or trained statistical staff. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies. This rule does not change those requirements.

The AMS is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

In addition, USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

Further, the Board's meetings were widely publicized throughout the hazelnut industry and all interested persons were invited to attend the meetings and participate in Board deliberations. Like all Board meetings, those held on August 24 and November 15, 2006, were public meetings and all entities, both large and small, were able to express their views on this issue.

An interim final rule concerning this action was published in the **Federal Register** on January 22, 2007. Copies of this rule were mailed by the Board's staff to all Board members. In addition, the rule was made available through the Internet by the Office of the Federal Register. A 60-day comment period ending March 23, 2007, was provided to allow interested parties to respond to the rule. No comments were received.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *http://www.ams.usda.gov/fv/moab.html.* Any questions about the compliance guide should be sent to Jay Guerber at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant material presented, including the information and recommendation submitted by the Board and other available information, it is hereby found that finalizing the interim final rule, without change, as published in the **Federal Register** (72 FR 2599, January 22, 2007) will tend to effectuate the declared policy of the Act.

List of Subjects in 7 CFR Part 982

Filberts, Hazelnuts, Marketing agreements, Nuts, Reporting and recordkeeping requirements.

PART 982—HAZELNUTS GROWN IN OREGON AND WASHINGTON

■ Accordingly, the interim final rule amending 7 CFR part 982 which was published at 72 FR 2599 on January 22, 2007, is adopted as a final rule without change.

Dated: April 25, 2007.

Lloyd C. Day,

Administrator, Agricultural Marketing Service.

[FR Doc. E7–8235 Filed 4–30–07; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2007–27014; Directorate Identifier 2006–NM–253–AD; Amendment 39–15041; AD 2007–09–09]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A330 Airplanes and Model A340–200 and –300 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for the products listed above. This AD results from mandatory continuing airworthiness information (MCAI) issued by an airworthiness authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as un-damped extension of the main landing gear (MLG), potentially leading to loss of side stay integrity and then MLG collapse. We are issuing this AD to require actions to correct the unsafe condition on these products.

DATES: This AD becomes effective June 5, 2007.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of June 5, 2007.

ADDRESSES: You may examine the AD docket on the Internet at *http://dms.dot.gov* or in person at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Tim Backman, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–2797; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

The FAA is implementing a new process for streamlining the issuance of ADs related to MCAI. This streamlined process will allow us to adopt MCAI safety requirements in a more efficient manner and will reduce safety risks to the public. This process continues to allow all FAA AD issuance processes to meet legal, economic, Administrative Procedure Act, and **Federal Register** requirements. We also continue to meet our technical decision-making responsibilities to identify and correct unsafe conditions on U.S.-certificated products.

This AD references the MCAI and related service information that we considered in forming the engineering basis to correct the unsafe condition. The AD contains text copied from the MCAI and for this reason might not follow our plain language principles.

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM was published in the **Federal Register** on January 26, 2007 (72 FR 3759). That NPRM proposed to require replacement of the retraction link assembly. The MCAI states that during full-scale fatigue tests, the retraction link failed on the latest growth production standard MLG (main landing gear) prior to its expected life limit. Investigations confirm that the root cause of this premature fracture is due to high lug stress. The retraction link is included in the ALS (Airworthiness Limitation section) Part 1—Safe Life Airworthiness Limitation Item—and is currently limited to 35,200 flight cycles (FC). Its fracture causes un-damped extension of the MLG, potentially leading to loss of side stay integrity and

then MLG collapse, which constitutes an unsafe condition. The aim of the MCAI is to mandate the reduced retraction link life limit and replacement of any retraction link that has exceeded this new limit.

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

We reviewed the available data and determined that air safety and the public interest require adopting the AD as proposed.

Differences Between This AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable in a U.S. court of law. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have required different actions in this AD from those in the MCAI in order to follow our FAA policies. Any such differences are described in a separate paragraph of the AD. These requirements, if any, take precedence over the actions copied from the MCAI.

Costs of Compliance

We estimate that this AD will affect 28 products of U.S. registry. We also estimate that it will take about 10 work-hours per product to comply with this AD. The average labor rate is $80 per work-hour. Required parts will cost about $0 per product. Where the service information lists required parts costs that are covered under warranty, we have assumed that there will be no charge for these parts. As we do not control warranty coverage for affected parties, some parties may incur costs higher than estimated here. Based on these figures, we estimate the cost of this AD to the U.S. operators to be $22,400, or $800 per product.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866;

(2) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD Docket.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://dms.dot.gov*; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains the NPRM, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone (800) 647–5227) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new AD:

2007–09–09 Airbus: Amendment 39–15041. Docket No. FAA–2007–27014; Directorate Identifier 2006–NM–253–AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective June 5, 2007.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Airbus Model A330 airplanes, and Model A340–200 and -300 series airplanes, certificated in any category; all serial numbers fitted with MLG (main landing gear) retraction link Part Number (PN) 201489311 (LH (left-hand) side) or PN 201489312 (RH (right-hand) side).

Reason

(d) The MCAI states that during full-scale fatigue tests, the retraction link failed on the latest growth production standard MLG (main landing gear) prior to its expected life limit. Investigations confirm that the root cause of this premature fracture is due to high lug stress. The retraction link is included in the ALS (Airworthiness Limitation section) Part 1—Safe Life Airworthiness Limitation Item—and currently limited to 35,200 flight cycles (FC). Its fracture causes un-damped extension of the MLG, potentially leading to loss of side stay integrity and then MLG collapse, which constitutes an unsafe condition. The aim of the MCAI is to mandate the reduced retraction link life limit and replacement of any retraction link that has exceeded this new limit.

Actions and Compliance

(e) Unless already done, do the following actions.

(1) Prior to the accumulation of 8,300 total landings on the retraction link assembly or within 39 days after the effective date of this AD, whichever occurs later, replace the retraction link assembly in accordance with the instructions defined in Airbus All Operators Telex A330–32A3208, dated October 18, 2006; or Airbus All Operators Telex A340–32A4252, dated October 18, 2006; as applicable.

(2) Within 39 days after the effective date of this AD, report to Airbus the life accumulation information of each retraction link assembly affected by this AD in accordance with Airbus All Operators Telex A330–32A3208, dated October 18, 2006; or Airbus All Operators Telex A340–32A4252, dated October 18, 2006; as applicable.

Note 1: This reduced life limit will be incorporated within the next revision of the Airbus A330/A340 ALS Part 1.

Other FAA AD Provisions

(f) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, ATTN: Tim Backman, Aerospace Engineer, 1601 Lind Avenue, SW., Renton, Washington 98057–3356, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Before using any AMOC approved in accordance with § 39.19 on any airplane to which the AMOC applies, notify the appropriate principal inspector in the FAA Flight Standards Certificate Holding District Office.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements:* For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act, the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120–0056.

Related Information

(g) Refer to MCAI European Aviation Safety Agency Emergency Airworthiness Directive 2006–0324–E, dated October 20, 2006; and Airbus All Operators Telex A330–32A3208, dated October 18, 2006; and Airbus All Operators Telex A340–32A4252, dated October 18, 2006, for related information.

Material Incorporated by Reference

(h) You must use Airbus All Operators Telex A330–32A3208, dated October 18, 2006; or Airbus All Operators Telex A340–32A4252, dated October 18, 2006; as applicable, to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France.

(3) You may review copies at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on April 23, 2007.

Stephen P. Boyd,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E7–8170 Filed 4–30–07; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2007–27838; Airspace Docket No. 07–ACE–6]

Modification of Class E Airspace; Hugoton, KS

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Direct final rule; request for comments.

SUMMARY: This action amends Title 14 Code of Federal regulations, part 71 (14 CFR 71) by modify Class E airspace at Hugoton Municipal Airport, KS. Standard Instrument Approach Procedures have been developed for Hugoton Municipal Airport, KS. Additional controlled airspace extending upward from the surface and upward from 700 feet above the surface of the earth is needed to contain aircraft executing these approaches. This action increases the area of the existing controlled airspace for Hugoton Municipal Airport, KS.

DATES: This direct final rule is effective on 0901 UTC, August 30, 2007. The Director of the Federal Register approves this incorporation by reference action under 1 CFR Part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments. Comments for inclusion in the Rules Docket must be received on or before June 1, 2007.

ADDRESSES: Send comments on this proposal to the Docket Management System, U.S. Department of Transportation, Room Plaza 401, 400 Seventh Street, SW., Washington, DC 20590–0001. You must identify the docket number FAA–2007–27838/Airspace Docket No. 07–ACE–6, at the beginning of your comments. You may also submit comments on the Internet at *http://dms.dot.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1–800–647–5527) is on the plaza level of the Department of Transportation NASSIF Building at the above address.

FOR FURTHER INFORMATION CONTACT: Grant Nichols, System Support, DOT Regional Headquarters Building, Federal Aviation Administration, 901 Locust, Kansas City, MO 64106; telephone: (816) 329–2522.

SUPPLEMENTARY INFORMATION: This amendment to 14 CFR 71 modifies the Class E airspace area at Hugoton Municipal Airport, KS. The radius of the Class E airspace area extending upward from 700 feet or more above the surface of the earth is expanded from within a 6.5-mile radius to within a 7.2-mile radius of the airport. This modification brings the legal description of the Hugoton Municipal Airport, KS Class E5 airspace area into compliance with FAA Orders 7400.2F and 8260.19C. Class E airspace areas extending upward from 700 feet or more above the surface of the earth are published in Paragraph 6005 of FAA Order 7400.9P, Airspace Designations and Reporting Points, dated September 1, 2006, and effective September 15, 2006, which is incorporated by reference in 14 CFR 71.1. of the same order. The Class E airspace designations listed in this document would be published subsequently in the Order.

The Direct Final Rule Procedure

The FAA anticipates that this regulation will not result in adverse or negative comment and, therefore, is issuing it as a direct final rule. Previous actions of this nature have not been controversial and have not resulted in adverse comments or objections. Unless a written adverse or negative comment or a written notice of intent to submit an adverse or negative comment is received within the comment period, the regulation will become effective on the date specified above. After the close of the comment period, the FAA will publish a document in the **Federal Register** indicating that no adverse or negative comments were received and confirming the date on which the final rule will become effective. If the FAA does receive, within the comment period, an adverse or negative comment, or written notice of intent to submit such a comment, a document withdrawing the direct final rule will be published in the **Federal Register**, and a notice of proposed rulemaking may be published with a new comment period.

Comment Invited

Interested parties are invited to participate in this rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both document numbers and be submitted in

triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2006–27838/Airspace Docket No. 07–ACE–6.'' The postcard will be date/time stamped and returned to the commenter.

Agency Findings

The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

The FAA has determined that this regulation is noncontroversial and unlikely to result in adverse or negative comments. For the reasons discussed in the preamble, I certify that this regulation (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority since it contains aircraft executing instrument approach procedures to Hugoton Municipal Airport, KS.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

■ Accordingly, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9P, dated September 1, 2006, and effective September 15, 2006, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ACE KS E5 Hugoton, KS

Hugoton Municipal Airport, KS
(Lat. 37[deg]09'47'' N., long. 101[deg]22'14'' W.)
Hugoton NDB
(Lat. 37[deg]09'49'' N., long. 101[deg]22'29'' W.)

That airspace extending upward from 700 feet above the surface within a 7.2-mile radius of Hugoton Municipal Airport and within 2.6 miles each side of the 199[deg] bearing from the Hugton NDB extending to 7 miles south of the airport.

* * * * *

Issued in Fort Worth, TX, on April 13, 2007.

Ronnie L. Uhlenhaker,

Manager, System Support Group, ATO Central Service Area.

[FR Doc. 07–2102 Filed 4–30–07; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2007–27837; Airspace Docket No. 07–ACE–5]

Modification of Class E Airspace; Bolivar, MO

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Direct final rule; request for comments.

SUMMARY: This action amends Title 14 Code of Federal Regulations, part 71 (14 CFR 71) by modifying Class E airspace at Bolivar Municipal Airport, MO. Standard Instrument Approach Procedures have been developed for Bolivar Municipal Airport, MO. Additional controlled airspace extending upward from the surface and upward from 700 feet above the surface of the earth is needed to contain aircraft executing these approaches. This action increases the area of the existing controlled airspace for Bolivar Municipal Airport, MO.

DATES: This direct final rule is effective on 0901 UTC, August 30, 2007. The Director of the Federal Register approves this incorporation by reference action under 1 CFR Part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments. Comments for inclusion in the Rules Docket must be received on or before June 1, 2007.

ADDRESSES: Send comments on this proposal to the Docket Management System, U.S. Department of Transportation, Room Plaza 401, Seventh Street, SW., Washington, DC 20509–0001. You must identify the docket number FAA–2007–27837/Airspace Docket No. 07–ACE–5, at the beginning of your comments. You may also submit comments on the Internet at *http://dms.dot.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1–800–647–5527) is on the plaza level of the Department of Transportation NASSIF Building at the above address.

FOR FURTHER INFORMATION CONTACT: Grant Nichols, System Support, DOT Regional Headquarters Building, Federal Aviation Administration, 901 Locust, Kansas City, MO 64106; telephone: (816) 329–2522.

SUPPLEMENTARY INFORMATION: This amendment to 14 CFR 71 modifies the Class E airspace area at Bolivar Municipal Airport, MO. The radius of the Class E airspace area extending upward from 700 feet or more above the surface of the earth is expanded from within a 6.3-mile radius to within a 7.2-mile radius of the airport. This modification brings the legal description of the Bolivar Municipal Airport, MO Class E5 airspace area into compliance with FAA Orders 7400.2F and 8260.19C. Class E airspace areas extending upward from 700 feet or more above the surface of the earth are published in Paragraph 6005 of FAA Order 7400.9P, Airspace Designations and Reporting Points, dated September 1, 2006, and effective September 15, 2006, which is incorporated by reference in 14 CFR 71.1. of the same order. The Class E airspace designations listed in this document would be published subsequently in the Order.

The Direct Final Rule Procedure

The FAA anticipates that this regulation will not result in adverse or negative comment and, therefore, is issuing it as a direct final rule. Previous actions of this nature have not been

controversial and have not resulted in adverse comments or objections. Unless a written adverse or negative comment or a written notice of intent to submit an adverse or negative comment is received within the comment period, the regulation will become effective on the date specified above. After the close of the comment period, the FAA will publish a document in the **Federal Register** indicating that no adverse or negative comments were received and confirming the date on which the final rule will become effective. If the FAA does receive, within the comment period, an adverse or negative comment, or written notice of intent to submit such a comment, a document withdrawing the direct final rule will be published in the **Federal Register**, and a notice of proposed rulemaking may be published with a new comment period.

Comment Invited

Interested parties are invited to participate in this rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement if made: ''Comments to Docket No. FAA–2006–27837/Airspace Docket No. 07–ACE–5.'' The postcard will be date/time stamped and returned to the commenter.

Agency Findings

The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

The FAA has determined that this regulation is noncontroversial and unlikely to result in adverse or negative comments. For the reasons discussed in the preamble, I certify that this regulation (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority since it contains aircraft executing instrument approach procedures to Bolivar Municipal Airport, MO.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

■ Accordingly, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9P, dated September 1, 2006, and effective September 15, 2006, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ACE MO E5 Bolivar, MO

Bolivar Municipal Airport, MO
(Lat. 37[deg]35'43'' N., long. 93[deg]20'52'' W.)

That airspace extending upward from 700 feet above the surface within a 7.2-mile radius of the Bolivar Municipal Airport.

* * * * *

Issued in Forth Worth, TX, on April 13, 2007.

Ronnie L. Uhlenhaker,

Manager, System Support Group, ATO Central Service Area.

[FR Doc. 07–2101 Filed 4–30–07; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 30548, Amdt. No. 3216]

Standard Instrument Approach Procedures, Weather Takeoff Minimums; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) and/or Weather Takeoff Minimums for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, addition of new obstacles, or changes in air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective May 1, 2007. The compliance date for each SIAP and/or Weather Takeoff Minimums is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of May 1, 2007.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination—

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591;

2. The FAA Regional Office of the region in which the affected airport is located;

3. The National Flight Procedures Office, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA). For

information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal—register/code—of—federal—regulations/ibr—locations.html*.

For Purchase—Individual SIAP and Weather Takeoff Minimums copies may be obtained from:

1. FAA Public Inquiry Center (APA–200), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591; or

2. The FAA Regional Office of the region in which the affected airport is located.

By Subscription—Copies of all SIAPs and Weather Takeoff Minimums mailed once every 2 weeks, are for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

FOR FURTHER INFORMATION CONTACT: Donald P. Pate, Flight Procedure Standards Branch (AFS–420), Flight Technologies and Programs Division, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd. Oklahoma City, OK. 73169 (Mail Address: P.O. Box 25082 Oklahoma City, OK. 73125) telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This amendment to Title 14 of the Code of Federal Regulations, Part 97 (14 CFR part 97), establishes, amends, suspends, or revokes SIAPs and/or Weather Takeoff Minimums. The complete regulatory description of each SIAP and/or Weather Takeoff Minimums is contained in official FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR part 97.20. The applicable FAA Forms are identified as FAA Forms 8260–3, 8260–4, 8260–5 and 8260–15A. Materials incorporated by reference are available for examination or purchase as stated above.

The large number of SIAPs and/or Weather Takeoff Minimums, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs and/or Weather Takeoff Minimums but refer to their depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP and/or Weather Takeoff Minimums contained in FAA form documents is unnecessary. The provisions of this amendment state the affected CFR sections, with the types and effective dates of the SIAPs and/or Weather Takeoff Minimums. This amendment also identifies the airport, its location, the procedure identification and the amendment number.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP and/or Weather Takeoff Minimums as contained in the transmittal. Some SIAP and/or Weather Takeoff Minimums amendments may have been previously issued by the FAA in a Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for some SIAP, and/or Weather Takeoff Minimums amendments may require making them effective in less than 30 days. For the remaining SIAPs and/or Weather Takeoff Minimums, an effective date at least 30 days after publication is provided.

Further, the SIAPs and/or Weather Takeoff Minimums contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPs and/or Weather Takeoff Minimums, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs and/or Weather Takeoff Minimums and safety in air commerce, I find that notice and public procedure before adopting these SIAPs and/or Weather Takeoff Minimums are impracticable and contrary to the public interest and, where applicable, that good cause exists for making some SIAPs and/or Weather Takeoff Minimums effective in less than 30 days.

Conclusion

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, and Navigation (Air).

Issued in Washington, DC on April 20, 2007.

James J. Ballough,

Director, Flight Standards Service.

Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me, under Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures and Weather Takeoff Minimums effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

Effective 05 JUL 2007

Kotzebue, AK, Ralph Wien Memorial, ILS OR LOC/DME RWY 9, Amdt 1
Kotzebue, AK, Ralph Wien Memorial, RNAV (GPS) RWY 9, Amdt 1
Kotzebue, AK, Ralph Wien Memorial, RNAV (GPS) RWY 27, Amdt 1
Kotzebue, AK, Ralph Wien Memorial, VOR/DME RWY 9, Amdt 5
Kotzebue, AK, Ralph Wien Memorial, VOR/DME Y RWY 27, Amdt 1
Kotzebue, AK, Ralph Wien Memorial, VOR/DME Z RWY 27, Amdt 1
Kotzebue, AK, Ralph Wien Memorial, VOR RWY 9, Amdt 4
Kotzebue, AK, Ralph Wien Memorial, VOR RWY 27, Amdt 4
Kotzebue, AK, Ralph Wien Memorial, Takeoff Minimums & Obstacle DP, Amdt 3
Ruby, AK, Ruby, RNAV (GPS) RWY 3, Amdt 1
Ruby, AK, Ruby, RNAV (GPS) RWY 21, Amdt 1
Fort Lauderdale, FL, Fort Lauderdale-Executive, Takeoff Minimums & Obstacle DP, Amdt 2
Fort Myers, FL, Page Field, RNAV (GPS) RWY 13, Orig
Fort Myers, FL, Page Field, GPS RWY 13, Orig, CANCELLED
Indianapolis, IN, Greenwood Muni, RNAV (GPS) RWY 1, Amdt 1
Indianapolis, IN, Greenwood Muni, RNAV (GPS) RWY 19, Amdt 1
Indianapolis, IN, Greenwood Muni, Takeoff Minimums & Obstacle DP, Amdt 2
Logansport, IN, Logansport/Cass County, Takeoff Minumums & Obstacle DP, Orig

Logansport, IN, Logansport/Cass County, RNAV (GPS) RWY 9, Orig
Logansport, IN, Logansport/Cass County, RNAV (GPS) RWY 27, Orig
Logansport, IN, Logansport/Cass County, GPS RWY 9, Orig, CANCELLED
Logansport, IN, Logansport/Cass County, GPS RWY 27, Orig, CANCELLED
Great Falls, MT, Great Falls Intl, ILS OR LOC/DME RWY 3, Amdt 3
Great Falls, MT, Great Falls Intl, RNAV (GPS) RWY 3, Amdt 1
Harrison, OH, Cincinnati West, Takeoff Minimums & Textual DP, Amdt 2
Greenville, SC, Greenville Downtown, ILS OR LOC RWY 1, Amdt 29
Greenville, SC, Greenville Downtown, RNAV (GPS) RWY 19, Orig
Greenville, SC, Greenville Downtown, NDB RWY 1, Amdt 22
Gallatin, TN, Sumner County Regional, RADAR–1, Amdt 4, CANCELLED
Lexington, TN, Franklin Wilkins, Takeoff Minimums and Obstacle DP, Orig, CANCELLED
Nashville, TN, Nashville International, RADAR–1, Amdt 22, CANCELLED
Parsons, TN, Scott Field, Takeoff Minimums and Obstacle DP, Orig, CANCELLED
Bellingham, WA, Bellingham Intl, Takeoff Minimums & Textual DP, Amdt 5

Effective 30 AUG 2007

Monroe, NC, Monroe Regional, RNAV (GPS) RWY 5, Amdt 1A
Columbus, OH, Ohio State University, NDB RWY 27L, Amdt 6B, CANCELLED

The FAA published an Amendment in Docket No. 30545 Amdt No. 3214 to Part 97 of the Federal Aviation Regulations (Vol 72, FR No. 72, page 18867, dated, April 16, 2007) Under Section 97.15 effective 10 May 2007, which is hereby rescinded:

Los Angeles, CA, Los Angeles Intl, Takeoff Minimums and Textual DP, Amdt 11

[FR Doc. E7–8014 Filed 4–30–07; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9322]

RIN 1545–BG26

Anti-Avoidance and Anti-Loss Reimportation Rules Applicable Following a Loss on Disposition of Stock of Consolidated Subsidiaries; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to final and temporary regulations.

SUMMARY: This document contains corrections to final and temporary regulations that was published in the **Federal Register** on Tuesday, April 10, 2007 (71 FR 17804) providing guidance to corporations filing consolidated returns and applying an anti-avoidance rule and revising an anti-loss reimportation rule that applies following a disposition of stock of a subsidiary at a loss.

FOR FURTHER INFORMATION CONTACT: Theresa Abell, (202) 622–7700 or Phoebe Bennett, (202) 622–7770 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

The final and temporary regulations (TD 9322) that are the subject of these corrections are under section 1502 of the Internal Revenue Code.

Need for Correction

As published, these final and temporary regulations (TD 9322) contain errors that may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, these final and temporary regulations (TD 9322) that were the subject of FR Doc. E7–6541, are corrected as follows:

1. On page 17805, column 1, in the preamble, under the paragraph heading ''*Background and Explanation of Provisions*'' paragraph 2, line 6 from the bottom of the column, the language ''the loss reimportation rule is also'' is corrected to read ''the anti-loss reimportation rule is also''.

2. On page 17805, column 2, in the preamble, under the paragraph heading ''*Special Analyses*'', line 5 from the top of the column, the language ''U.S.C. 553(b)(B) that prior notice and'' is corrected to read ''U.S.C. 553(b)(3)(B) that prior notice and''.

3. On page 17805, column 2, in the preamble, under the paragraph heading ''*Special Analyses*'', line 16 from the top of the column, the language ''reference notice of the proposed'' is corrected to read ''reference notice of proposed''.

LaNita Van Dyke,

Branch Chief, Publications and Regulations Branch, Legal Processing Division, Office of Associate Chief Counsel (Procedure and Administration).

[FR Doc. E7–8316 Filed 4–30–07; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[CGD05–07–038]

RIN 1625–AA00

Security Zone: Queen of England Visit, Jamestown Island, VA.; Correction

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule; correction.

SUMMARY: The U. S. Coast Guard published a rule in the **Federal Register** of April 23, 2007, a document concerning the Queen of England's visit to Jamestown Island, VA. Inadvertently § 165.T07–038 was numbered incorrectly. This document corrects that number.

DATES: This rule is effective from 8 a.m. on May 3, 2007, until 8 p.m. on May 4, 2007.

FOR FURTHER INFORMATION CONTACT: LCDR Thomas Tarrants, Enforcement Branch Chief, U.S. Coast Guard Sector Hampton Roads, Virginia at (757) 483–8571.

SUPPLEMENTARY INFORMATION: The U.S. Coast Guard published a document in the **Federal Register** of April 23, 2007, (72 FR 20051) inadvertently numbering the section § 165.T07–038. This correction removes the number published on April 23, 2007.

In rule FR Doc. CGD05–07–038 published on April 23, 2007, (72 FR 20051) make the following correction. On page 20052, in two places, remove the number § 165.T07–038 and put in place of that number § 165.T05–038.

Dated: April 25, 2007.

Steve Venckus,

Chief, Office of Regulations and Administrative Law.

[FR Doc. E7–8315 Filed 4–30–07; 8:45 am]

BILLING CODE 4910–15–P

Proposed Rules

Federal Register
Vol. 72, No. 83
Tuesday, May 1, 2007

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Parts 315 and 752

RIN 3206–AL30

Career and Career-Conditional Employment and Adverse Actions

AGENCY: Office of Personnel Management.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Office of Personnel Management (OPM) proposes to amend its regulations governing Federal adverse actions. The proposed regulations would conform the adverse action rules regarding employee coverage to binding judicial decisions interpreting the underlying statute.

DATES: Submit comments on or before July 2, 2007.

ADDRESSES: Send or deliver written comments to Ana A. Mazzi, Deputy Associate Director for Workforce Relations and Accountability Policy, Office of Personnel Management, 1900 E Street, NW., Room 7H28, Washington, DC 20415; by FAX to 202–606–2613; or by e-mail to *CWRAP@opm.gov.*

FOR FURTHER INFORMATION CONTACT: Sharon L. Mayhew by telephone at (202) 606–2930; by FAX at (202) 606–2613; or by e-mail at *CWRAP@opm.gov.*

SUPPLEMENTARY INFORMATION: Section 7514 of title 5, United States Code (U.S.C.), provides the statutory authority for OPM to prescribe regulations pertaining to adverse actions in the competitive or excepted service. In addition, these regulations are found at title 5, Code of Federal Regulations (CFR), part 752, subpart D, and are the subject of this interim final rule. Corresponding and related regulations pertaining to probationary periods are found at 5 CFR part 315, subpart H, and also are the subject of this proposed rule.

Amendments To Clarify Adverse Action Rules Regarding Employee Coverage

Background—New Interpretation of the Statute—Van Wersch and McCormick

Two decisions of the U.S. Court of Appeals for the Federal Circuit (Federal Circuit or Court), *Van Wersch* v. *Department of Health and Human Services*, 197 F.3d 1144 (Fed. Cir. 1999) and *McCormick* v. *Department of the Air Force*, 307 F.3d 1339 (Fed. Cir. 2002), *pet. for reh'g in banc denied*, 329 F.3d 1354 (Fed. Cir. 2003) caused us to revise the pre-existing interpretation of 5 U.S.C. 7511(a)(1), and invalidated portions of the adverse actions regulations at 5 CFR part 752. The effect of these Federal Circuit opinions is to provide additional procedural and appeal rights to individuals who are working in a probationary period in the competitive service and in a trial period in the excepted service. OPM is proposing to change its regulations to conform to the Court's interpretation of the statute.

The pertinent statutory text appears below:

5 U.S.C. Sec. 7511. Definitions; application
(a) For the purpose of this subchapter—
(1) ''Employee'' means—
(A) An individual in the competitive service—
(i) Who is not serving a probationary or trial period under an initial appointment; or
(ii) Who has completed 1 year of current continuous service under other than a temporary appointment limited to 1 year or less;
(B) A preference eligible in the excepted service who has completed 1 year of current continuous service in the same or similar positions—
(i) In an Executive agency; or
(ii) In the United States Postal Service or Postal Rate Commission; and
(C) An individual in the excepted service (other than a preference eligible)—
(i) Who is not serving a probationary or trial period under an initial appointment pending conversion to the competitive service; or
(ii) Who has completed 2 years of current continuous service in the same or similar positions in an Executive agency under other than a temporary appointment limited to 2 years or less;

An individual who meets this definition of ''employee'' is entitled to certain procedural and appeal rights when he or she is the subject of an adverse action (*e.g.*, removal, certain types of suspension, reduction in grade, reduction in pay, and furlough of 30 days or less). These rights include: (1) At least 30 days' advance written notice of the reason for a proposed adverse action; (2) a reasonable time, but not less than 7 days, to answer orally and in writing; (3) the right to be represented by an attorney or other representative; (4) a written decision and the specific reasons for the decision at the earliest practicable date; and (5) a right to appeal to the Merit Systems Protection Board (MSPB or the Board). Individuals who do not meet this definition are not afforded all of these rights.

Before the Court issued *Van Wersch* and *McCormick*, OPM and the MSPB interpreted the statute to exclude probationary or trial period employees from receiving the same rights as employees who have completed their probationary or trial period. Probationary and trial periods are essential for management to assess an individual's performance prior to granting full employment rights. Specifically, OPM regulations did not afford full employment rights to an individual in the competitive service who failed to meet one of the conditions of 5 U.S.C. 7511(a)(1)(A), or an individual in the excepted service who failed to meet one of the conditions of 5 U.S.C. 7511(a)(1)(C). Thus, for example, an individual in the competitive service serving in a probationary period was not an ''employee'' for purposes of 5 CFR part 752, nor was an individual who did not complete one year of current, continuous service under other than a temporary appointment limited to one year or less. Likewise, an individual in the excepted service serving a probationary or trial period was not an ''employee'' for purposes of 5 CFR part 752, nor was a nonpreference eligible who did not complete two years of current, continuous service under other than a temporary appointment limited to two years or less.

Contrary to this interpretation, the Federal Circuit in *Van Wersch* held that an individual in the excepted service could meet the definition of ''employee'' if he or she met *either* of the two conditions listed at 5 U.S.C. 7511(a)(1)(C). Ms. Van Wersch was removed from Federal employment for alleged unacceptable conduct. At the time of her removal, she was serving a probationary or trial period under an initial excepted service appointment

pending conversion to the competitive service and therefore was excluded from coverage under 5 U.S.C. 7511(a)(1)(C)(i). Ms. Van Wersch had been hired as a Clerk-Typist pursuant to 5 CFR 213.3102(u), which allowed agencies to appoint severely handicapped persons to excepted service positions. Employees hired under this authority may qualify for conversion to competitive status after they have completed two years of satisfactory service. Ms. Van Wersch served over two years in this position but was not converted to competitive status.

The Federal Circuit addressed the question of whether an individual, like Ms. Van Wersch, serving in a probationary or trial period and therefore excluded from the definition of ''employee'' under 5 U.S.C. 7511(a)(1)(C)(i), could still be considered an employee, with full adverse action rights, if she met only the criteria of 5 U.S.C. 7511(a)(1)(C)(ii). The Government argued that Congress had not intended to extend employee appeal rights to excepted service personnel, such as Ms. Van Wersch, who were serving in probationary or trial positions pending conversion to the competitive service. While recognizing that the Government made a compelling case for its reading of the statute based on the legislative history, the Court rejected the Government's argument, holding that Congress had not used language that effectuated the putative legislative intent and that courts are not authorized to look at Congressional intent when the language of the statute was clear and unambiguous. *Van Wersch* v. *Department of Health and Human Services*, 197 F.3d 1144, 1152 (Fed.Cir. 1999). Because Ms. Van Wersch literally met what the Court determined was an alternative definition of ''employee'' in 5 U.S.C. 7511(a)(1)(C)(ii), the Court concluded that she was an employee under the statute and therefore had the right to appeal her termination to the MSPB. *Id.* at 1151. The Federal Circuit also noted that ''if Congress determines that individuals in Ms. Van Wersch's position should not have the right to appeal adverse actions to the Board, it can amend § 7511(a)(1)(C) so as to compel a result different from the one we reach today.'' *Id.* at 1152.

The Federal Circuit applied the *Van Wersch* analysis to the competitive service in *McCormick* v. *Department of the Air Force*, 307 F.3d 1339 (Fed. Cir. 2002), *pet. for reh'g denied*, 329 F. 3d 1354 (Fed. Cir. 2003) and found the appellant qualified as an employee under 5 U.S.C. 7511(a)(1)(A)(ii) even though she failed to qualify under (i). Ms. McCormick previously was a competitive service employee at the Department of Health and Human Services (DHHS) before voluntarily moving to a new position at the Department of the Air Force. Her new competitive service appointment was subject to a one-year probationary period. Ms. McCormick was terminated during this probationary period. On appeal, Ms. McCormick argued that, while she did not meet the definition of an employee under 5 U.S.C. 7511(a)(1)(A)(i), she did meet the definition of 5 U.S.C. 7511(a)(1)(A)(ii), based on her DHHS employment.

The Court held that ''[t]he panel is bound by the court's earlier decision in *Van Wersch*.'' *Id.* at 1342. Thus, the Federal Circuit concluded that Ms. McCormick met the definition of ''employee'' under 5 U.S.C. 7511(a)(1)(A)(ii), having completed more than 1 year of current or continuous service under other than a temporary appointment limited to 1 year or less, and therefore was to be afforded all the rights of an employee. *Id.* at 1343.

Conforming the Adverse Action Regulations to the New Statutory Interpretation

As yet, Congress has not accepted the Court's invitation to amend these provisions. Therefore, to eliminate potential confusion, OPM proposes to amend the regulations at 5 CFR part 752 to conform to the existing Federal Circuit case law described above.

[0]We therefore propose to make four amendments to the text of paragraphs (c) and (d) of 5 CFR 752.401, to clarify the definition of ''employee'' for purposes of the adverse action rules. Three amendments are required to conform to the holding in *McCormick*, and one amendment is necessary to conform to *Van Wersch*

First, to conform with *McCormick's* holding that an individual serving in the competitive service on a probationary period may meet the definition of an ''employee,'' we propose to amend paragraph (c)(1) at § 752.401, to state that a career or career conditional employee in the competitive service who is not serving a probationary or trial period is a covered employee. We propose adding the phrase, ''career or career conditional'' here to address recent cases in which individuals serving in positions not subject to a probationary or trial period have attempted to establish that they are ''employees'' within the meaning of the statute because they are not serving a probationary or trial period under an initial appointment. See e.g., *Johnson* v. *Department of Veterans Affairs*, 99 MSPR 362 (2005). Such a conclusion would produce an unreasonable result in that every temporary appointee would have a right to advance notice, an opportunity to respond, and the right of appeal, on his or her first day of work. This is contrary to OPM's interpretation of the phrase, ''who is not serving a probationary or trial period under an initial appointment,'' as applying only to individuals serving in positions that are subject to a probationary or trial period. The legislative history supports this interpretation and, accordingly, OPM explicitly continues its existing interpretation of the statute in this respect. We note that the MSPB adopted this interpretation in *Johnson*.

Second, we propose to add a new § 752.401(d)(13) to clarify that a competitive service employee who is serving a probationary or trial period does not meet the definition of ''employee'' unless he or she has completed one year of current continuous service under other than a temporary appointment limited to one year or less.

The *McCormick* decision also requires an amendment to paragraph (c)(2) of 5 CFR 752.401, which currently identifies as a covered employee, an individual ''in the competitive service serving in an appointment that requires no probationary or trial period, and who has completed one year of current continuous service in the same or similar positions under other than a temporary appointment limited to 1 year or less.'' We propose to remove the phrase, ''serving in an appointment that requires no probationary or trial period, and'' to comport with the Court's ruling in *McCormick*.

To comply with *Van Wersch*, the final amendment would add modifying language to paragraph (d)(11) to make it clear that a nonpreference eligible excepted service employee, who is serving a probationary or trial period pending conversion to the competitive service, does not meet the definition of ''employee'' unless he or she has completed two years of current continuous service under other than a temporary appointment limited to two years or less.

Conforming Part 315 to the New Statutory Interpretation

We are also proposing to change part 315, Career and Career Conditional Employment, to make the regulations governing probationary periods consistent with the change in the definition of ''covered employee.''

Additional Regulatory Clarification Required by Payano

OPM is proposing to remove the phrase ''in the same or similar positions'' from the regulation at the amended paragraph 5 CFR 752.401(c)(2), and also from the definition of ''current continuous employment'' at 5 CFR 752.402. This change addresses language in the current regulations concerning individuals in the competitive service that requires that ''continuous service'' be in ''the same or similar positions.'' That language is not found in the statute. This issue arose in administrative litigation before the MSPB. *See Payano* v. *Department of Justice*, 100 MSPR 74 (2005). The issue in that case was whether an employee could ''tack on'' the time served in another competitive service position that was not the same as or similar to the position from which he was removed, for the purpose of determining whether or not he was an employee. The MSPB held that an agency was required to take this time into account in determining whether a person in the competitive service was an ''employee.'' OPM has determined that this interpretation of the statute is the best one and is proposing to change the regulations to reflect that view.

Public Participation

OPM invites interested persons to participate in this proposed rulemaking by submitting written comments, data, or views.

Before finalizing these proposed amendments, we will consider all comments received on or before the closing date for comments. We will consider comments filed late if it is possible to do so without incurring expense or delay. We may change these proposed amendments in light of the comments we receive.

E.O. 12866, Regulatory Review

The Office of Management and Budget has reviewed this rule in accordance with E.O. 12866.

Regulatory Flexibility Act

OPM has determined these amendments will not have a significant economic impact on a substantial number of small entities because they will apply only to Federal agencies and employees.

List of Subjects

5 CFR Part 315

Government employees.

5 CFR Part 752

Administrative practice and procedure, Government employees.

Office of Personnel Management.

Linda M. Springer,

Director.

Accordingly, OPM proposes to amend parts 315 and 752 of title 5, Code of Federal Regulations, as follows:

PART 315—CAREER AND CAREER CONDITIONAL EMPLOYMENT

1. The authority for part 315 continues to read:

Authority: 5 U.S.C. 1302, 3301, and 3302; E.O. 10577, 3 CFR, 1954–1958 Comp., p. 218, unless otherwise noted; and E.O. 13162; secs, 315.601 and 315.609 also issued under 22 U.S.C. 3651 and 3652. Secs. 315.602 and 315.604 also issued under 5 U.S.C. 1104. Sec 315.603 also issued under 5 U.S.C. 8151. Sec 315.605 also issued under E.O. 12034, 3 CFR, 1978 Comp., p. 111. Sec 315.606 also issued under E.O. 11219, 3 CFR, 1964–1965 Comp., p. 303. Sec 315.607 also issued under 22 U.S.C. 2506. Sec 315.608 also issued under E.O. 12721, 3 CFR, 1990 Comp., p. 293. Sec. 315.610 also issued under 5 U.S.C. 3304(d). Sec 315.611 also issued under Section 511, Pub. L. 106–117, 113 Stat. 1575–76. Sec 315.708 also issued under E.O. 13318. Sec. 315.710 also issued under E.O. 12596, 3 CFR, 1987 Comp., p. 229. Subpart I also issued under 5 U.S.C. 3321, E.O. 12107, 3 CFR, 1978 Comp., p. 264.

2. Revise § 315.803 to read as follows:

§ 315.803 Agency action during probationary period (general).

(a) The agency shall utilize the probationary period as fully as possible to determine the fitness of the employee and shall terminate his services during this period if he fails to demonstrate fully his qualifications for continued employment.

(b) Termination of an individual serving a probationary period must be taken in accordance with subpart D of part 752 of this chapter if the individual has completed one year of current continuous service under other than a temporary appointment limited to 1 year or less and is not otherwise excluded by the provisions of that subpart.

3. Revise § 315.804 (a) to read as follows:

§ 315.804 Termination of probationers for unsatisfactory performance or conduct.

(a) Subject to § 315.803(b), when an agency decides to terminate an employee serving a probationary or trial period because his work performance or conduct during this period fails to demonstrate his fitness or his qualifications for continued employment, it shall terminate his services by notifying him in writing as to why he is being separated and the effective date of the action. The information in the notice as to why the employee is being terminated shall, as a minimum, consist of the agency's conclusions as to the inadequacies of his performance or conduct.

* * * * *

4. Revise § 315.805 introductory text to read as follows:

§ 315.805 Termination of probationers for conditions arising before appointment.

Subject to § 315.803(b), when an agency proposes to terminate an employee serving a probationary or trial period for reasons based in whole or in part on conditions arising before his appointment, the employee is entitled to the following:

* * * * *

PART 752—ADVERSE ACTIONS

1. The authority for part 752 continues to read:

Authority: 5 U.S.C. 7504, 7514, and 7543.

2. Revise § 752.401 (c)(1) and (2), (d)(11) and (12), and add (d)(13) to read as follows:

§ 752.401 Coverage.

(a) * * *

(b) * * *

(c) * * *

(1) A career or career conditional employee in the competitive service who is not serving a probationary or trial period;

(2) An employee in the competitive service who has completed 1 year of current continuous service under other than a temporary appointment limited to 1 year or less;

* * * * *

(d) * * *

* * * * *

(11) A nonpreference eligible employee serving a probationary or trial period under an initial appointment in the excepted service pending conversion to the competitive service, unless they meet the requirements of paragraph (c)(5) of this section;

(12) An employee whose agency or position has been excluded from the appointing provisions of title 5, United States Code, by separate statutory authority in the absence of any provision to place the employee within the coverage of chapter 75 of title 5, United States Code; and

(13) An employee in the competitive service serving a probationary or trial period, unless they meet the requirements of paragraph (c)(2) of this section.

3. Revise § 752.402 (b) to read as follows:

§ 752.402 Definitions.

(a) * * *

(b) Current continuous employment means a period of employment or service immediately preceding an adverse action without a break in Federal civilian employment of a workday.

* * * * *

[FR Doc. E7–8061 Filed 4–30–07; 8:45 am]

BILLING CODE 6325–39–P

DEPARTMENT OF AGRICULTURE

Grain Inspection, Packers and Stockyards Administration

7 CFR Part 810

RIN 0580–AA96

Request for Public Comment on the United States Standards for Soybeans

AGENCY: Grain Inspection, Packers and Stockyards Administration, USDA.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: We are initiating a review of the United States Standards for Soybeans to determine their effectiveness and responsiveness to current grain industry needs. Numerous changes have occurred in the breeding and production practices of soybeans as well as in the technology used to harvest, process, and test soybeans, and in the marketing practices of soybeans. As a result, soybean producer groups have asked us to initiate a review of the soybean standards. In order to ensure that the standards and subsequent grading practices remain relevant, we invite interested persons to submit comments and supporting information to assist in the evaluation of current standards and grading practices for soybeans and in the development of any recommendations for change.

DATES: We will consider comments that we receive by July 2, 2007.

ADDRESSES: We invite you to submit comments on this advance notice of proposed rulemaking. You may submit comments by any of the following methods:

<bullet≤ *E-Mail:* Send comments via electronic mail to *comments.gipsa@usda.gov.*

<bullet≤ *Mail:* Send hardcopy written comments to Tess Butler, GIPSA, USDA, 1400 Independence Avenue, SW., Room 1647–S, Washington, DC 20250–3604.

<bullet≤ *Fax:* Send comments by facsimile transmission to: (202) 690–2755.

<bullet≤ *Hand Delivery or Courier:* Deliver comments to: Tess Butler, GIPSA, USDA, 1400 Independence Avenue, SW., Room 1647–S, Washington, DC 20250–3604.

<bullet≤ *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the online instructions for submitting comments.

<bullet≤ *Instructions:* All comments should make reference to the date and page number of this issue of the **Federal Register**.

<bullet≤ *Read Comments:* All comments will be available for public inspection in the above office during regular business hours (7 CFR 1.27(b)).

FOR FURTHER INFORMATION CONTACT: Rebecca Riese at GIPSA, USDA, 1400 Independence Avenue, SW., Washington, DC 20250–3630; Telephone (202) 720–4116; Fax Number (202) 720–7883; e-mail *Rebecca.A.Riese@usda.gov.*

SUPPLEMENTARY INFORMATION:

Executive Order 12866

This rule has been determined to be exempt from the purpose of Executive Order 12866, and therefore has not been reviewed by the Office of Management and Budget (OMB).

We established the U.S. soybean standards on November 20, 1940, under the authority of the United States Grain Standards Act (7 U.S.C. 76). To further facilitate the marketing of U.S. soybeans, we revised the standards in 1994 and 2006. The 2006 revision becomes effective September 1, 2007.

In 1994, we revised the reporting requirements of splits (broken soybeans where more than one fourth of the soybean removed and that are not damaged), reduced the U.S. Sample Grade criteria for stones and glass, established a special grade Purple Mottled or Stained, eliminated the grade limitation on materially weathered soybeans, clarified references to Mixed soybeans, and established a cumulative total for U.S. Sample Grade factors. In 2006, we published a Final Rule (71 FR 52403–52406), to be effective September 1, 2007, that changes the minimum test weight per bushel (TW) from a grade determining factor to an informational factor. Various factors are identified for soybeans and are used to determine the level of the grade of the shipment of soybeans. TW will continue to be measured, but no longer used to determine grade; it will be provided as additional information on the certificate unless the applicant for inspection service for the soybeans indicates that the information is not needed. As an informational factor TW may continue to be of interest and specified in contracts for soybean shipments.

The standards serve as the fundamental starting point to define U.S. soybean quality in the global marketplace. They include definitions, the basic principles governing application of standards, such as the type of sample used for a particular quality analysis, grades and grade requirements, and special grades and special grade requirements, such as for Garlicky soybeans and Purple Mottled or Stained soybeans. Official procedures for how the various grading factors are determined are provided in the Grain Inspection Handbook, Book II, Chapter 10, ''Soybeans.'' Official procedures may be viewed and printed from the GIPSA Web site at: *http://archive.gipsa.usda.gov/reference-library/handbooks/grain-insp/grbook2/soybean.pdf.*) Also included are standardized procedures for additional soybean quality attributes not used to determine grade, such as oil and protein content. Together, the grading and testing standards allow buyers and sellers to communicate quality requirements for trade, compare soybean quality using equivalent forms of measurement, and assist in the establishment of price.

GIPSA's grading and inspection services, as provided through a network of federal, state, and private laboratories, determine the quality and condition of soybeans. These determinations are performed in accordance with applicable standards using approved methodologies, and can be applied at any point in the marketing chain. The current testing technology for quality attributes, such as oil and protein content, is rapid and reliable, yielding consistent results. In addition, GIPSA issues certificates describing the quality and condition of the graded soybeans that are accepted as evidence in all Federal courts. U.S. soybean standards, and the affiliated grading and testing services offered by GIPSA, verify that the seller's commodity meets specified requirements, and that customers receive the quality they expect.

Over time, numerous changes have occurred in the breeding and production practices of soybeans as well as in the technology used to harvest, process, and test soybeans, and in the marketing practices of soybeans. In this rapidly evolving market, we need to ensure that the U.S. soybean standards and associated grading procedures remain relevant. Therefore, we are issuing this advance notice of proposed rulemaking to invite comments from all interested persons for input and suggestions for

amendments to the soybean standards and associated grading procedures so that the standards remain applicable and best facilitate the marketing of U.S. soybeans. We are requesting comments, supporting data, and other information in response to questions on the following topics, as well as about all aspects of the soybean standards and inspection procedures. This information may be viewed and printed from the GIPSA Web site at: *http://archive.gipsa.usda.gov/reference-library/handbooks/grain-insp/grbook2/soybean.pdf.*

Foreign Material

The soybean standards currently define foreign material (FM) as: ''All matter that passes through an 8/64 round-hole sieve and all matter other than soybeans remaining in the sieved sample after sieving according to procedures prescribed in FGIS instructions.''

When separating FM (impurities) from soybeans, inspectors follow a process that entails using a combined mechanical (sieve) and manual separation procedure. Specifically, inspectors first handpick the 1,000 to 1,050-gram soybean sample for coarse foreign material (*e.g.*, whole kernels of corn, cockleburs, sticks, and pods). Next, inspectors cut down the sample (free of coarse FM) to a portion of 125 grams. Using an approved shaker or hand sieve, the inspector sieves the sample with an 8/64'' round-hole sieve. The inspector must handpick the material other than soybeans from the material remaining on top of the sieve and add it to the material that passed through the sieve (fine FM).

It is important to note that when inspectors see soybean pods in the sample, they remove the soybeans from the pods and only the pod is considered as foreign material. Further, soybean hulls which remain on top of the sieve are not considered FM; whereas small broken pieces of soybeans, which pass through the sieve, are considered as FM.

Finally, inspectors calculate the total amount of FM by adding the percentage of coarse FM to the percentage of fine FM. (This procedure may be viewed and printed from the GIPSA Web site at: *http://archive.gipsa.usda.gov/reference-library/handbooks/grain-insp/grbook2/soybean.pdf.*)

The following is a series of questions about the FM definition and procedure:

1. Is the definition of FM, as provided in the soybean standards, still sufficient for current marketing practices?

2. How does our method for separating FM from soybeans compare to the commercial cleaning process? Please provide as much detail as possible as to how FM is determined in the market or for the segment of the market that you represent.

3. In order to provide a better representation of actual market value of soybeans, should we consider developing and adopting a fully-automated process to better reflect commercial cleaning capabilities? Please elaborate on the type of equipment (and sieves, if applicable) necessary for using such a procedure for separating FM from soybeans.

4. Do small broken pieces of soybeans have processing value? Should the procedure be amended so that brokens are not considered as FM?

5. Do processors have a method for removing soybeans from the pod? If not, should the procedure be amended so that pods, with or without soybeans in them, will be considered as FM?

6. In light of changes in the production practices of soybeans brought about by various technological developments, farm programs, and other factors, should the grading limits for FM be amended? What should the new grade limits be? Please provide a rationale for any changes, and if possible, project the quantifiable costs and benefits for the U.S. soybean market if the grade limits were amended.

Damage

According to our current inspection procedures, inspectors cross section soybeans and pieces of soybeans that are immature and have a thin, flat, wrinkled, or wafer-like appearance to determine if there is ''meat'' in the kernel. If there is ''meat'' in the kernel and the ''meat'' is not otherwise damaged, the inspector considers the soybean to be sound.

7. Do wafered kernels (wafers) containing minimal amounts of ''meat'' have processing value? If not, or if the value is appreciably reduced, should the procedure be amended so that wafers, to include soybeans with minimal amounts of meat, are considered damaged for inspection and grading purposes?

Other Factors

In the Official Inspection and Weighing System, we currently offer analyses or determinations for a number of official criteria factors for soybeans.

8. Are there other factors for which we should offer analyses/determinations that would provide better or more complete information to facilitate the marketing and/or processing of soybeans?

9. Since oil and protein content are considered to be the true determinants of value for soybean processing, should analysis of oil and protein content be mandatory, nongrade-determining factors that would be determined and reported on all official certificates for grade?

10. Are there certain aspects about the oil and protein content that would provide more meaningful information? For example, should we offer not only protein content, but also the amino acid profile of the protein?

11. Considering the rapid growth in biodiesel production, would the information exchange between sellers and buyers of soybeans be facilitated if standardized tests existed for attributes, such as fatty acids?

a. Please list the specific attributes.

b. Should we have a role in standardizing tests for the attributes listed? Should we assist only in the standardization of the tests (e.g., develop reference methods or improve existing reference methods) or should we make tests for these attributes available throughout the official system?

GIPSA has been working with life science companies in the pursuit of a standardized, rapid test for the determination of linolenic acid content in soybeans. Acres currently devoted to production of low linolenic acid soybean varieties are lower than previously anticipated. In 2006, these acres totaled approximately 750,000 out of the 72 million total planted soybean acres, less than 1 percent. However, seed distributors project acres devoted to production of low linolenic acid soybean varieties in 2007 to triple.

12. Should GIPSA continue to pursue a standardized, rapid test for the determination of linolenic acid content and, if so, why?

Visual Reference Images

In the determination of the grading factor total damage, inspectors look for a number of types of damage, including badly ground-damaged, badly weathered-damaged, diseased, frost-damaged, germ-damaged, heat-damaged, insect-bored, mold-damaged, sprout-damaged, stinkbug-stung, or otherwise materially damaged.

13. Are these the right types of damage, and are visual reference images/interpretive lines that are currently used to determine the various types of damages reflective of the level of quality desired in the marketplace? (Visual reference images/interpretive lines may be viewed on the GIPSA Web site at: *http://www.gipsa.usda.gov/GIPSA/webapp?area=home&subject=grpi&topic=sq-isd-soybeans.*)

Inspectors also rely on visual reference images to determine whether

a sample meets the general appearance criteria for the special grade designation ''Purple Mottled or Stained.''

14. In consideration of the fact that the overall appearance of the product is an important consideration for some customers, should we create other general appearance images? What appearance factors are of greatest interest? (Visual reference images/general appearance factors may be viewed on the GIPSA Web site at: *http://www.gipsa.usda.gov/GIPSA/webapp?area=home&subject=grpi&topic=sq-isd*.)

Basis of Determination

As provided in 9 CFR 810.1603, Basis of determination, ''each determination of class, heat-damaged kernels, damaged kernels, splits, and soybeans of other colors is made on the basis of the grain when free from foreign material. Inspectors make other determinations not specifically provided for under the general provisions on the basis of the grain as a whole.'' For example, inspectors determine moisture content on the sample as a whole.

15. What basis of determination is used in the marketplace for the various factors? Why does the marketplace use that basis?

16. Would there be any positive or detrimental consequences if we were to determine all factors on the basis of a sample when free from foreign matter?

Food Grade Soybeans

17. Should we establish a separate standard, for example, U.S. Standards for Food Grade Soybeans or a separate grade level, class, or special grade within the existing soybeans standards for food-grade soybeans? Please provide as much detail as possible as to:

a. Explain why.

b. What would a new standard look like or what would the grade limits be for a new grade level?

We are committed to provide market-relevant soybean standards. We welcome your comments on these issues as well as any comments or suggestions on changes to the soybean standards and grading procedures.

Authority: 7 U.S.C. 71–87.

James E. Link,

Administrator, Grain Inspection, Packers and Stockyards Administration.

[FR Doc. E7–8291 Filed 4–30–07; 8:45 am]

BILLING CODE 3410–KD–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 929

[Docket No. AMS–FV–07–0034; FV07–929–1]

Cranberries Grown in the States of Massachusetts, Rhode Island, Connecticut, New Jersey, Wisconsin, Michigan, Minnesota, Oregon, Washington, and Long Island in the State of New York; Continuance Referendum

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Referendum order.

SUMMARY: This document directs that a continuance referendum be conducted among eligible growers of cranberries in the States of Massachusetts, Rhode Island, Connecticut, New Jersey, Wisconsin, Michigan, Minnesota, Oregon, Washington, and Long Island in the State of New York to determine whether they favor continuance of the marketing order regulating the handling of cranberries grown in the production area.

DATES: The referendum will be conducted from May 17 through May 31, 2007. To vote in this referendum, growers must have been engaged in producing cranberries within the production area during the period September 1, 2005, through August 31, 2006.

ADDRESSES: Copies of the marketing order may be obtained from USDA, Washington, DC Marketing Field Office, 4700 River Road, Unit 155, Riverdale, Maryland 20737, or the Office of the Docket Clerk, Marketing Order Administration Branch, Fruit and Vegetable Programs, Agricultural Marketing Service, U.S. Department of Agriculture, 1400 Independence Avenue, SW., Stop 0237, Washington, DC 20250–0237.

FOR FURTHER INFORMATION CONTACT: Patricia A. Petrella or Kenneth G. Johnson, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, Unit 155, 4700 River Road, Riverdale, MD 20737; telephone: (301) 734–5243, Fax: (301) 734–5275; or e-mail at: *Kenneth.Johnson@usda.gov* or *Patricia.Petrella@usda.gov*.

SUPPLEMENTARY INFORMATION: Pursuant to Marketing Order No. 929 (7 CFR part 929), hereinafter referred to as the ''order,'' and the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act,'' it is hereby directed that a referendum be conducted to ascertain whether continuance of the order is favored by growers. The referendum shall be conducted during the period May 17 through May 31, 2007, among eligible cranberry growers in the production area. Only growers that were engaged in the production of cranberries in the States of Massachusetts, Rhode Island, Connecticut, New Jersey, Wisconsin, Michigan, Minnesota, Oregon, Washington, and Long Island in the State of New York during the period of September 1, 2005, through August 31, 2006, may participate in the continuance referendum.

USDA has determined that continuance referenda are an effective means for determining whether growers favor continuation of marketing order programs. The USDA would not consider termination of the order if more than 50 percent of the growers who vote in the referendum and growers of more than 50 percent of the volume of cranberries represented in the referendum favor continuance of their program.

In evaluating the merits of continuance versus termination, the USDA will not only consider the results of the continuance referendum. The USDA will also consider all other relevant information concerning the operation of the order and the relative benefits and disadvantages to growers, processors, and consumers in order to determine whether continued operation of the order would tend to effectuate the declared policy of the Act.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the ballot materials used in the referendum herein ordered have been previously approved by the Office of Management and Budget (OMB) under OMB No. 0581–0189, OMB Generic Fruit Crops. It has been estimated that it will take an average of 20 minutes for each of the approximately 1,100 producers of cranberries in the production area to cast a ballot. Participation is voluntary. Ballots postmarked after May 31, 2007, will be marked invalid and not included in the vote tabulation.

Kenneth G. Johnson, Patricia A. Petrella and Dawana Clark of the Washington, DC Marketing Field Office, Fruit and Vegetable Programs, Agricultural Marketing Service, USDA, are hereby designated as the referendum agents of USDA to conduct such referendum. The procedure applicable to the referendum shall be the ''Procedure for the Conduct of Referenda in Connection With

Marketing Orders for Fruits, Vegetables, and Nuts Pursuant to the Agricultural Marketing Agreement Act of 1937, as Amended'' (7 CFR 900.400 *et seq.*).

Ballots will be mailed to all growers of record and may also be obtained from the referendum agents and from their appointees.

List of Subjects in 7 CFR Part 929

Cranberries, Marketing agreements, Reporting and recordkeeping requirements.

Authority: 7 U.S.C. 601–674.

Dated: April 25, 2007.

Lloyd C. Day,

Administrator, Agricultural Marketing Service.

[FR Doc. E7–8233 Filed 4–30–07; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 35

[Docket Nos. RM05–10–000 and AD04–13–000]

Imbalance Provisions for Intermittent Resources; Assessing the State of Wind Energy in Wholesale Electricity Markets

Issued April 25, 2007.

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Withdrawal of notice of proposed rulemaking.

SUMMARY: The Federal Energy Regulatory Commission is withdrawing its proposal to amend its regulations to require public utilities to append to their open access transmission tariffs (OATTs) an intermittent generator imbalance service schedule in light of the imbalance-related reforms adopted in Order No. 890, 72 FR 12266 (Mar. 15, 2007).

DATES: The notice of proposed rulemaking published on April 14, 2005, at 70 FR 21349, is withdrawn as of May 1, 2007.

FOR FURTHER INFORMATION CONTACT:

W. Mason Emnett (Legal Information), Office of the General Counsel—Energy Markets, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 502–6540.

Daniel Hedberg (Technical Information), Office of Energy Markets and Reliability, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 502–6243.

SUPPLEMENTARY INFORMATION:

Before Commissioners: Joseph T. Kelliher, Chairman; Suedeen G. Kelly, Marc Spitzer, Philip D. Moeller, and Jon Wellinghoff.

Withdrawal of Notice of Proposed Rulemaking

1. On April 14, 2005, the Commission issued a Notice of Proposed Rulemaking (NOPR) in this proceeding.[1] For the reasons set forth below, we are withdrawing the NOPR and terminating this rulemaking.

2. In the NOPR, the Commission proposed to clarify and amend imbalance-related provisions in the *pro forma* Open Access Transmission Tariff (OATT) as applied to intermittent resources.[2] The Commission concluded that, although the number of intermittent resources had grown since the adoption of the *pro forma* OATT in Order No. 888,[3] such resources were historically hesitant to take service under the *pro forma* OATT, thereby accessing broader markets, due to the application of imbalance provisions that were designed to apply to resources with the ability to control fuel input and thus schedule their energy with precision. The Commission concluded that the imbalance provisions of the Order No. 888 *pro forma* OATT may no longer be just, reasonable or not unduly discriminatory or preferential as applied to intermittent resources that by nature are weather-driven.[4] The Commission therefore proposed to establish a standard schedule under the *pro forma* OATT to address generator imbalances solely for intermittent resources and sought comment on issues related to that proposal.

3. Since issuance of the NOPR, the Commission has completed its OATT reform rulemaking in Docket Nos. RM05–25–000, *et al.*, issuing Order No. 890 on February 16, 2007.[5] Among other things, Order No. 890 adopted a new Schedule 9 to govern generator imbalances. Under Schedule 9, imbalance charges ''must be based on incremental cost or some multiple therefore'' and ''must provide an incentive for accurate scheduling, such as by increasing the percentage of the adder above (and below) incremental cost as the deviation becomes larger.'' [6] Of particular relevance to this proceeding, the Commission also required that imbalance provisions ''account for the special circumstances presented by intermittent generators and their limited ability to precisely forecast or control generation levels, such as waiving the more punitive adders associated with higher deviations.'' [7]

4. As a result of the imbalance-related reforms adopted in Order No. 890, and in particular the requirement that generator imbalance provisions in each transmission provider's OATT take into account an intermittent resources' limited ability to forecast or control generation levels, the Commission concludes that it is no longer necessary to address the NOPR proposal to add to the *pro forma* OATT a generator imbalance schedule solely for intermittent resources. The reforms adopted in Order No. 890 adequately ensure that the imbalance provisions of the *pro forma* OATT will not result in service to intermittent resources that is unjust, unreasonable, or unduly discriminatory or preferential.

5. The Commission therefore withdraws the NOPR and terminates this rulemaking proceeding.

The Commission orders:

Docket No. RM05–10–000 is hereby terminated.

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[1] *Imbalance Provisions for Intermittent Resources Assessing the State of Wind Energy in Wholesale Electricity Markets*, Notice of Proposed Rulemaking, 70 FR 21349 (Apr. 26, 2005), FERC Stats. & Regs. ¶ 32,581 (2005).

[2] For purposes of the NOPR, an intermittent resource was defined as an electric generator that is not dispatchable and cannot store its fuel source and therefore cannot respond to changes in system demand or respond to transmission security constraints.

[3] *Promoting Wholesale Competition Through Open Access Non-discriminatory Transmission Services by Public Utilities and Recovery of Stranded Costs by Public Utilities and Transmitting Utilities*, Order No. 888, 61 FR 21,540 (May 10, 1996), FERC Stats. & Regs. ¶ 31,036 (1996), *order on reh'g*, Order No. 888–A, 62 FR 12,274 (March 14, 1997), FERC Stats. & Regs. ¶ 31,048 (1997), *order on reh'g*, Order No. 888–B, 81 FERC ¶ 61,248 (1997), *order on reh'g*, Order No. 888–C, 82 FERC ¶ 61,046 (1998), *aff'd in relevant part, remanded in part on other grounds sub nom. Transmission Access Policy Study Group, et al.* v. *FERC*, 225 F.3d 667 (D.C. Cir. 2000), *aff'd sub nom. New York* v. *FERC*, 535 U.S. 1 (2002).

[4] The Commission began exploring these issues at a technical conference held on December 1, 2004, in Denver, Colorado in Docket No. AD04–13–000. Other transmission-related issues regarding wind energy were also discussed at the technical conference and in post-technical conference comments, such as the interconnection process, credits for transmission upgrades, and adoption of a conditional firm transmission product. These issues were not addressed in the NOPR, which was limited to the imbalance provisions of the *pro forma* OATT as they relate to intermittent resources.

[5] *See Preventing Undue Discrimination and Preference in Transmission Service,* Order No. 890, 72 FR 12266 (March 15, 2007), FERC Stats. & Regs. ¶ 31,241 (2007), *reh'g pending.*

[6] Order No. 890 at P 663.

[7] *Id.* The Commission also adopted a standard definition of intermittent resource that is identical to that proposed in this proceeding. *See Id.* at P 666.

By the Commission.

Kimberly D. Bose,

Secretary.

[FR Doc. E7–8236 Filed 4–30–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[COTP San Diego 07–225]

RIN 1625–AA00

Safety Zone; Labor Day Fireworks, Lower Colorado River, Laughlin, NV

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes establishing a temporary safety zone on the navigable waters of the Lower Colorado River, Laughlin, NV, in support of a Labor Day fireworks display near the AVI Resort and Casino. The safety zone is necessary to provide for the safety of the crew, spectators, participants of the event, participating vessels and other vessels and users of the waterway. Persons and vessels will be prohibited from entering into, transiting through, or anchoring within this safety zone unless authorized by the Captain of the Port, or his designated representative.

DATES: Comments and related material must reach the Coast Guard on or before July 31, 2007.

ADDRESSES: You may mail comments and related material to Commander (SPW), Attn: Waterways Management Division, Coast Guard Sector San Diego, 2710 N. Harbor Drive, San Diego, CA 92101–1028. Marine Events, Prevention Department, maintains the public docket for this rulemaking. Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, will become part of this docket and will be available for inspection or copying at Coast Guard Sector San Diego between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Chief Petty Officer Eric Carroll, Waterways Management, U.S. Coast Guard Sector San Diego, CA, at telephone (619) 278–7277.

SUPPLEMENTARY INFORMATION:

Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related material. If you do so, please include your name and address, identify the docket number for this rulemaking [COTP San Diego 07–225], indicate the specific section of this document to which each comment applies, and give the reason for each comment. Please submit all comments and related material in an unbound format, no larger than 8½ by 11 inches, suitable for copying. If you would like to know they reached us, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of them.

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for a meeting by writing to Coast Guard Sector San Diego at the address under **ADDRESSES** explaining why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

The Coast Guard proposes establishing a temporary safety zone on the navigable waters of the Lower Colorado River, Laughlin, NV, in support of a Labor Day fireworks show in the navigation channel of the Lower Colorado River, Laughlin, NV. The fireworks show is being sponsored by AVI Resort and Casino. The safety zone will be set at a 980-foot radius around the anchored firing barge. This temporary safety zone is necessary to provide for the safety of the show's crew, spectators, participants of the event, participating vessels, and other vessels and users of the waterway.

Discussion of Proposed Rule

The event involves one anchored barge, which will be used as a platform for launching of fireworks. The safety zone is required because the barge's planned firing location is in the navigation channel. This safety zone would be enforced from 8 p.m. through 9:30 p.m. on September 2, 2007.

The limits of this temporary safety zone include all areas within 980 feet of the firing location adjacent to the AVI Resort and Casino centered in the navigational channel between Laughlin Bridge and the northwest point of the AVI Resort and Casino Cove in position: 35[deg]00[min]45[sec] N, 114[deg]38[min]16[sec] W.

U.S. Coast Guard personnel would enforce this safety zone. Other Federal, State, or local agencies may assist the Coast Guard, including the Coast Guard Auxiliary. Vessels or persons violating this rule would be subject to both criminal and civil penalties.

Regulatory Evaluation

This proposed rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not ''significant'' under the regulatory policies and procedures of the Department of Homeland Security (DHS).

We expect the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation under the regulatory policies and procedures of DHS is unnecessary. Although the safety zone will restrict boating traffic within the navigable waters of the Lower Colorado River, Laughlin, NV, the effect of this regulation will not be significant as the safety zone will encompass only a small portion of the waterway and will be very short in duration. The entities most likely to be affected are pleasure craft engaged in recreational activities and sightseeing. As such, the Coast Guard expects the economic impact of this rule to be minimal.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities. This rule will affect the following entities, some of which may be small entities: the owners or operators of vessels intending to transit or anchor in a portion of the Lower Colorado River, Laughlin, NV, from 8 p.m. to 9:30 p.m. on September 2, 2007.

This safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons. The safety zone only encompasses a small portion of the waterway, it is short in duration at a late hour when commercial traffic is low, and the Captain of the Port may authorize entry into the zone, if necessary.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact Chief Petty Officer Eric Carroll, Waterways Management, U.S. Coast Guard Sector San Diego at telephone (619) 278–7277. The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this proposed rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This proposed rule would not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this proposed rule under Commandant Instruction M16475.lD and Department of Homeland Security Management Directive 5100.1, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, we believe that this rule should be categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation because we would be establishing a safety zone. A preliminary ''Environmental Analysis Check List'' and ''Categorical Exclusion Determination'' are available in the docket where indicated under **ADDRESSES**. Comments on this section will be considered before we make the final decision on whether the rule should be categorically excluded from further environmental review.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

2. Add § 165.T11–179 to read as follows:

§ 165.T11–179 Safety Zone; Labor Day Fireworks, Lower Colorado River, Laughlin, NV.

(a) *Location.* The limits of this temporary safety zone include all areas within 980 feet of the anchored firing barge. The firing barge will be anchored adjacent to the AVI Resort and Casino,

centered in the navigational channel between Laughlin Bridge and the northwest point of the AVI Resort and Casino Cove, Lower Colorado River, Laughlin, NV in position 35[deg]00'45'' N, 114[deg]38'16'' W.

(b) *Effective Period.* This safety zone will be in effect from 8 p.m. until the end of the fireworks show on September 02, 2007. The event is scheduled to conclude no later than 9:30 p.m. However, if the display concludes prior to the scheduled termination time, the Captain of the Port will cease enforcement of this safety zone and will announce that fact via Broadcast Notice to Mariners.

(c) *Regulations.* In accordance with the general regulations in § 165.23 of this part, entry into, transit through, or anchoring within this zone by all vessels is prohibited, unless authorized by the Captain of the Port, or his designated representative. Mariners requesting permission to transit through the safety zone may request authorization to do so from the U.S. Coast Guard Patrol Commander. The U.S. Coast Guard Patrol Commander may be contacted via VHF–FM Channel 16.

(d) *Enforcement.* All persons and vessels shall comply with the instructions of the Coast Guard Captain of the Port or the designated on-scene patrol personnel. Patrol personnel can be comprised of commissioned, warrant, and petty officers of the Coast Guard onboard Coast Guard, Coast Guard Auxiliary, local, State, and Federal law enforcement vessels. Upon being hailed by U.S. Coast Guard patrol personnel by siren, radio, flashing light, or other means, the operator of a vessel shall proceed as directed. The Coast Guard may be assisted by other Federal, State, or local agencies.

Dated: April 5, 2007.

C.V. Strangfeld,

Captain, U.S. Coast Guard, Captain of the Port, San Diego.

[FR Doc. E7–8307 Filed 4–30–07; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[COTP San Diego 07–125]

RIN 1625–AA00

Safety Zone; Independence Day Fireworks, Lower Colorado River, Laughlin, NV

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes establishing a temporary safety zone on the navigable waters of the Lower Colorado River, Laughlin, NV, in support of a Independence Day fireworks display near the AVI Resort and Casino. The safety zone is necessary to provide for the safety of the crew, spectators, participants of the event, participating vessels and other vessels and users of the waterway. Persons and vessels will be prohibited from entering into, transiting through, or anchoring within this safety zone unless authorized by the Captain of the Port, or his designated representative.

DATES: Comments and related material must reach the Coast Guard on or before May 31, 2007.

ADDRESSES: You may mail comments and related material to Commander (SPW), Attn: Waterways Management Division, Coast Guard Sector San Diego, 2710 N. Harbor Drive, San Diego, CA 92101–1028. Marine Events, Prevention Department, maintains the public docket for this rulemaking. Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, will become part of this docket and will be available for inspection or copying at Coast Guard Sector San Diego between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Chief Petty Officer Eric Carroll, Waterways Management, U.S. Coast Guard Sector San Diego, CA, at telephone (619) 278–7277.

SUPPLEMENTARY INFORMATION:

Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related material. If you do so, please include your name and address, identify the docket number for this rulemaking [COTP San Diego 07–125], indicate the specific section of this document to which each comment applies, and give the reason for each comment. Please submit all comments and related material in an unbound format, no larger than 8½ by 11 inches, suitable for copying. If you would like to know they reached us, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of them.

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for a meeting by writing to Coast Guard Sector San Diego at the address under **ADDRESSES** explaining why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

The Coast Guard proposes establishing a temporary safety zone on the navigable waters of the Lower Colorado River, Laughlin, NV, in support of an Independence Day fireworks show in the navigation channel of the Lower Colorado River, Laughlin, NV. The fireworks show is being sponsored by AVI Resort and Casino. The safety zone will be set at a 980-foot radius around the anchored firing barge. This temporary safety zone is necessary to provide for the safety of the show's crew, spectators, participants of the event, participating vessels, and other vessels and users of the waterway.

Discussion of Proposed Rule

The event involves one anchored barge, which will be used as a platform for launching of fireworks. The safety zone is required because the barge's planned firing location is in the navigation channel. This safety zone would be enforced from 8 p.m. through 9:45 p.m. on July 7, 2007.

The limits of this temporary safety zone include all areas within 980 feet of the firing location adjacent to the AVI Resort and Casino centered in the navigational channel between Laughlin Bridge and the northwest point of the AVI Resort and Casino Cove in position: 35[deg]00[min]45[sec] N, 114[deg]38[min]16[sec] W.

U.S. Coast Guard personnel would enforce this safety zone. Other Federal, State, or local agencies may assist the Coast Guard, including the Coast Guard Auxiliary. Vessels or persons violating this rule would be subject to both criminal and civil penalties.

Regulatory Evaluation

This proposed rule is not a ''significant regulatory action'' under

section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not ''significant'' under the regulatory policies and procedures of the Department of Homeland Security (DHS).

We expect the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation under the regulatory policies and procedures of DHS is unnecessary. Although the safety zone will restrict boating traffic within the navigable waters of the Lower Colorado River, Laughlin, NV, the effect of this regulation will not be significant as the safety zone will encompass only a small portion of the waterway and will be very short in duration. The entities most likely to be affected are pleasure craft engaged in recreational activities and sightseeing. As such, the Coast Guard expects the economic impact of this rule to be minimal.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities. This rule will affect the following entities, some of which may be small entities: The owners or operators of vessels intending to transit or anchor in a portion of the Lower Colorado River, Laughlin, NV, from 8 p.m. to 9:45 p.m. on July 7, 2007.

This safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons. The safety zone only encompasses a small portion of the waterway, it is short in duration at a late hour when commercial traffic is low, and the Captain of the Port may authorize entry into the zone, if necessary.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact Chief Petty Officer Eric Carroll, Waterways Management, U.S. Coast Guard Sector San Diego at telephone (619) 278–7277. The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this proposed rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This proposed rule would not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or

adopted by voluntary consensus standards bodies.

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this proposed rule under Commandant Instruction M16475.lD and Department of Homeland Security Management Directive 5100.1, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, we believe that this rule should be categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation because we would be establishing a safety zone. A preliminary ''Environmental Analysis Check List'' and a draft ''Categorical Exclusion Determination'' are available in the docket where indicated under **ADDRESSES**. Comments on this section will be considered before we make the final decision on whether the rule should be categorically excluded from further environmental review.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

2. Add § 165.T11–178 to read as follows:

§ 165.T11–178 Safety Zone; Independence Day Fireworks, Lower Colorado River, Laughlin, NV.

(a) *Location.* The limits of this temporary safety zone include all areas within 980 feet of the anchored firing barge. The firing barge will be anchored adjacent to the AVI Resort and Casino, centered in the navigational channel between Laughlin Bridge and the northwest point of the AVI Resort and Casino Cove, Lower Colorado River, Laughlin, NV in position 35[deg]00'45'' N, 114[deg]38'16'' W.

(b) *Effective Period.* This safety zone will be in effect from 8 p.m. until the end of the fireworks show on July 7, 2007. The event is scheduled to conclude no later than 9:45 p.m. However, if the display concludes prior to the scheduled termination time, the Captain of the Port will cease enforcement of this safety zone and will announce that fact via Broadcast Notice to Mariners.

(c) *Regulations.* In accordance with the general regulations in § 165.23 of this part, entry into, transit through, or anchoring within this zone by all vessels is prohibited, unless authorized by the Captain of the Port, or his designated representative. Mariners requesting permission to transit through the safety zone may request authorization to do so from the U.S. Coast Guard Patrol Commander. The U.S. Coast Guard Patrol Commander may be contacted via VHF–FM Channel 16.

(d) *Enforcement.* All persons and vessels shall comply with the instructions of the Coast Guard Captain of the Port or the designated on-scene patrol personnel. Patrol personnel can be comprised of commissioned, warrant, and petty officers of the Coast Guard onboard Coast Guard, Coast Guard Auxiliary, local, State, and Federal law enforcement vessels. Upon being hailed by U.S. Coast Guard patrol personnel by siren, radio, flashing light, or other means, the operator of a vessel shall proceed as directed. The Coast Guard may be assisted by other Federal, State, or local agencies.

Dated: April 5, 2007.

C.V. Strangfeld,

Captain, U.S. Coast Guard, Captain of the Port, San Diego.

[FR Doc. E7–8317 Filed 4–30–07; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA–R05–OAR–2006–0546; FRL–8308–1]

Approval and Promulgation of Ohio SO_2 Air Quality Implementation Plans and Designation of Areas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve an assortment of rules, submitted by Ohio on May 16, 2006, setting limits on sulfur dioxide (SO_2) emissions. Most significantly, EPA is proposing to approve rules for Franklin, Stark and Summit Counties and for one source in Sandusky County that are currently regulated under limits that EPA promulgated in 1976 as a Federal Implementation Plan (FIP). If finalized, this action would provide that the entire FIP for SO_2 in Ohio would be superseded by approved State limits. Consequently, EPA is proposing to rescind the entire FIP. EPA is also proposing to approve several substantive rule revisions and to approve numerous Ohio rules that update various company names and unit identifications. Finally, since this rulemaking resolves the issues which led a court to remand the designation for a portion of Summit County to EPA for reconsideration, EPA is proposing to promulgate a designation of attainment for the presently undesignated portion of this county.

DATES: Comments must be received on or before May 31, 2007.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2007–0546, by one of the following methods:

1. *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.

2. *E-mail: mooney.john@epa.gov.*

3. *Fax:* (312) 886–5824.

4. *Mail:* John M. Mooney, Chief, Criteria Pollutant Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

5. *Hand Delivery:* John M. Mooney, Chief, Criteria Pollutant Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m. excluding Federal holidays.

Instructions: Direct your comments to Docket ID No. EPA–R05–OAR–2006–0546. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or e-mail. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *www.regulations.gov* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional instructions on submitting comments, go to Section I of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. We recommend that you telephone John Summerhays at (312) 886–6067 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT: John Summerhays, Criteria Pollutant Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–6067, *summerhays.john@epa.gov.*

SUPPLEMENTARY INFORMATION: This supplementary information section is arranged as follows:

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C. Additional Substantive Rule Revisions
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I. Background

Ohio submitted its original State Implementation Plan on January 30, 1972, which EPA partially approved on May 31, 1972, and fully approved on September 22, 1972. After a court remanded this approval for EPA to solicit public comments on the rulemaking, Ohio withdrew its submittal of rules for SO_2. In the absence of State rules for SO_2, EPA promulgated a Federal Implementation Plan (FIP) for SO_2 on August 27, 1976, with numerous subsequent amendments. The FIP provided limits for 55 Ohio counties.

On September 12, 1979, Ohio submitted a plan with limits for SO_2 in all 88 Ohio counties. This plan relied on a set of rules that included 6 rules governing general provisions such as test methods and compliance schedules, plus one rule for each of the 88 counties setting emission limits for sources in the county. On January 27, 1981, at 46 FR 8481, EPA approved most of the 6 general rules and approved rules for parts of 13 counties and all of 61 counties. That rulemaking action also disapproved rules for Summit County because EPA concluded that the limits did not provide for attainment. That rulemaking notice provided further history of regulation of SO_2 emissions in Ohio as of that date.

On April 20, 1982, at 47 FR 16784, EPA approved rules for parts of 3 additional counties and all of another three additional counties. EPA approved rules for an additional county on June 30, 1982, at 47 FR 28377. EPA approved subsequently submitted Ohio SO_2 rules on May 20, 1988 (at 53 FR 18087), August 23, 1994 (at 59 FR 43290), October 9, 1996 (at 61 FR 52882), March 30, 1998 (at 63 FR 15091), June 5, 2000 (at 65 FR 35577), January 31, 2002 (at 67 FR 4669), February 2, 2004 (at 69 FR 4856), and January 28, 2005 (at 70 FR 4023).

As a result of these prior rulemakings, EPA has approved State rules for all sources in 84 of Ohio's 88 counties and for all but one source in an 85th county. Counties for which sources remain subject to the FIP include Franklin County (full county), Stark County (full county), Summit County (full county), and Sandusky County (only for Martin Marietta). Ohio submitted further rules on May 16, 2006, most significantly including State rules to replace these Federal rules.

In 1978, EPA designated numerous areas in Ohio as nonattainment for the SO_2 air quality standard. EPA interprets section 107(d)(3)(E)(ii) of the Clean Air Act, as amended in 1990, to require approval of state regulations rather than promulgation of a FIP as a prerequisite for redesignation of areas from nonattainment to attainment. Thus, some of Ohio's prior submittals of state rules to replace federal rules served in part to satisfy this prerequisite for redesignation from nonattainment to attainment.

As stated in 40 CFR 52.1881(a), ''[w]here USEPA has approved the State's sulfur dioxide plan, those regulations supersede the federal sulfur dioxide plan contained in [40 CFR 52.1881(b)] and 40 CFR 52.1882.'' On June 29, 1995, at 60 FR 33915, EPA rescinded numerous federally promulgated Ohio SO_2 rules, observing that the ''superseded rules have no effect and are unenforceable, and thus no longer need be retained in the CFR.'' On January 28, 2005, at 70 FR 4023, in conjunction with approving State rules for several counties, EPA rescinded the corresponding federally promulgated rules (where applicable) that were superseded by these State rules. As a result, what remains of the federally promulgated rules are the following:

—40 CFR 52.1881 paragraphs (b)(1) through (b)(6), providing definitions and other general provisions,
—40 CFR 52.1881 paragraphs (b)(7) through (b)(10), providing limits for sources in Franklin, Sandusky (Martin-Marietta only), Stark, and Summit Counties, respectively, and
—40 CFR 52.1882, providing schedules for compliance with the federally promulgated limits.

Ohio law requires that the State review its regulations every five years. Ohio conducted this review and concluded that amendments were warranted for 4 of its 6 general rules and 40 of its county-specific rules. Since the regulations remain necessary for the State to continue to attain the SO_2 air quality standards, and since only in a few cases did information become available warranting a revision to emission limits, most of the revisions reflect administrative changes such as updating company names and correcting unit identifications. Ohio adopted these rules effective January 13, 2006, and submitted them to USEPA on May 16, 2006.

Ohio currently has no areas designated nonattainment for SO_2. The final area redesignated from

nonattainment to attainment was in Cuyahoga County, which was redesignated on January 28, 2005, at 70 FR 4023.

However, a portion of one county, Summit County, has no designation. As the result of a 1980 remand by the Court of Appeals for the 6th Circuit, in *PPG Industries, Inc.* v. *Costle* (630 F.2d 462), this area has been undesignated pending EPA's review of modeling analyses for the area. Such a review is an inherent part of EPA's review of the adequacy of the rules Ohio submitted regulating SO_2 emissions in Summit County. Consequently, in conjunction with submitting a rule for SO_2 emissions in Summit County, Ohio also requested that EPA reestablish a designation for this area, requesting that EPA designate this area as attaining the SO_2 standard.

In 1981, EPA published multiple rulemaking notices that led to EPA taking no action on provisions of Ohio SO_2 regulations that provided for compliance on a 30-day average basis. EPA has approved only a stack test method (reflecting a 3-hour average) and other tests reflecting averaging times of generally 24 hours or less. On February 11, 1980, at 45 FR 9101, EPA published notice that EPA would nevertheless give priority to cases in which companies were violating SO_2 limits on a 30-day average basis or exceeding the limit on any day by more than 50 percent. This policy remains in effect, and today's rulemaking makes no change with respect to this issue.

II. Review of Ohio's Submittal

On May 16, 2006, Ohio EPA submitted 4 amended general SO_2 rules and 40 county-specific SO_2 rules. The county-specific rules include 4 rules that were submitted to supersede remaining FIP rules, 4 rules that include substantive revisions to the limits, and 32 rules which only change company names or unit identifications or make other such administrative changes. Ohio supplemented this submittal with an email from William Spires to John Summerhays dated February 22, 2007, providing supplemental information regarding a source in Sandusky County and requesting that EPA establish a designation of attainment for Summit County.

A. General Rules

Ohio submitted revisions to four of its six general SO_2 rules: Ohio Administrative Code (OAC) 3745–18–01, 3745–18–02, 3745–18–03, and 3745–18–06. Rule 3745–18–01, entitled ''Definitions,'' was modified to update the referencing of test methods in the Code of Federal Regulations, to retain only a general referencing of methods adopted by the American Society for Testing and Materials, to update the Web site from which the Code of Federal Regulations may be obtained, and to make editorial changes in the referencing of relevant material. Rule 3745–18–02, entitled ''Ambient air quality standards—sulfur dioxide,'' was modified only to add a preliminary note referring readers to Rule 3745–18–01 to find dates for applicable reference material and to specify which location of 40 CFR part 50 (namely, Appendix A) contains the test method to be used in assessing ambient air quality. Rule 3745–18–03, entitled ''Attainment dates and compliance time schedules,'' was revised to correct several facility identification numbers and to correct other referencing errors. The updated Web site in Rule 3745–18–01 is incorrect: Instead of ending ''ecfr'', the Web site ends in ''cfr,'' to read *http://www.access.gpo.gov/cfr* (or *http://www.access.gpo.gov/cfr*). However, this error does not change the stringency of any limits. Indeed, all of the changes to Rules 3745–18–01, 3745–18–02, and 3745–18–03 may be considered administrative changes that do not change the substance of the SIP. EPA believes that all of these revisions are approvable.

Rule 3745–18–06 was revised to add jet engine test stands to a list of source types that are exempt from the emission limits given in Ohio's rules for any day that the equipment burns only natural gas. EPA has approved this exemption as previously worded, on January 28, 2005, at 70 FR 4023 (see also 69 FR 41336, dated July 8, 2004). The first listed source type is fuel burning equipment. Thus, this rule revision may be considered simply a clarification that jet engine test stands shall have the exemption that fuel burning equipment has. In any case, the SO_2 emissions from burning natural gas from jet engine test stands is sufficiently low that this combustion need not be subject to any specific emission regulation. The rule was also subject to a minor rearrangement. EPA believes this rule is approvable.

B. Rules To Replace FIP Rules

As noted above, FIP rules remain in 4 counties: Franklin, Sandusky (applicable only to Martin Marietta), Stark, and Summit Counties. Ohio submitted rules for each of these counties to replace the FIP rules.

For Franklin and Summit Counties, Ohio amended its rules to assure that all sources with emission limits in the FIP have the same limits in the State rules. Criteria for EPA's review of these rules are described in guidance issued from the Director of the Air Quality Management Division to the Director of Region 5's Air and Radiation Division on September 28, 1994. This memorandum recommended approving State rules in place of FIP rules if three criteria are met:

1. That the FIP demonstrated the limits were adequately protective at the time of promulgation.

2. There is no evidence now that the FIP and associated emission limits are inadequate to protect the SO_2 national ambient air quality standards.

3. The rules do not relax existing emission limits. EPA believes that these criteria are satisfied, i.e., that limits were appropriately demonstrated at the time of FIP promulgation to provide for attainment, that no subsequent evidence suggests otherwise, and that the State's rules provide limits that are fully as stringent as the existing FIP limits. The State rules also establish limits for sources that are not included either in the FIP rules or in the modeling that demonstrated that the FIP limits provide for attainment. Therefore, EPA believes that the rules for Franklin and Summit County may be approved and may supersede the existing FIP rules.

As noted above, EPA disapproved the State's rules for Summit County in 1981, stating that modeling evidence indicated that the limits did not assure attainment. Those rules differed substantially from the FIP limits and relied on a separate modeling analysis. The prior disapproval did not in any way indicate inadequacy of the FIP limits to assure attainment. EPA continues to believe that the FIP limits for Summit County provide for attainment. Thus, since the State rules have been modified to reflect the FIP limits, EPA believes the rules now provide for attainment, and the prior disapproval is moot.

For Stark County, as with Franklin and Summit Counties, the State amended its rules as necessary for sources regulated under the FIP to have limits that match those of the FIP. The Stark County rules also tighten the limits for one source not regulated under the FIP, namely Canton Drop Forge. Modeling was conducted to assess impacts of this source and other nearby sources. This modeling used AERMOD, which is EPA's recommended model for this application. The modeling included emissions from all significant sources in this portion of Stark County. The modeling used 1988 to 1992 meteorological data for Akron, and the modeling considered the potential downwash effects of the buildings of

Canton Drop Forge and reflected the terrain elevations of the ambient receptor locations analyzed. Based on its review, EPA finds that this modeling was properly conducted and finds that the modeling demonstrates that the State's limits provide for attainment in this part of Stark County. For the rest of the County, EPA believes that modeling conducted in support of the FIP continues to represent a suitable demonstration that the remainder of the County will attain the standard.

For Sandusky County, only one source, Martin Marietta, remains subject to FIP rules. The FIP imposes a limit of 15.42 pounds of SO_2 per ton of material input into the lime kiln. Ohio's Rule 3745–18–78 (E) imposes a limit of 25 pounds per ton of product. A comparison of these limits requires a comparison of the quantity of material input to the quantity of lime produced. Ohio notes in its supplemental submittal that the weight ratio of limestone input to lime produced is commonly about two to one, and the ratio of total material input including fuel (coke and/or coal) is significantly higher than that. Since the FIP limit involves dividing emissions from each kiln by the larger quantity of input material, the corresponding limit on a per ton of product basis (i.e. the limit that would allow the same total emissions from the plant) would be a substantially higher number. In particular, the FIP limit corresponds to a limit on a per ton of product basis that is well over two times the number of pounds allowed on a per ton of input material basis, i.e. well over 30 pounds per ton of product. Thus, EPA believes that Ohio's limit is significantly more stringent. Furthermore, the Federal limit sets a limit on the emissions ''from any stack.'' The facility has multiple stacks, and the federal limit arguably allows 15.42 pounds per ton of material input from each stack, which would allow several times that much emissions in total. The state rule avoids this potential confusion by clearly imposing a limit on total emissions per ton of product. For these reasons, EPA believes that Ohio's limit may be approved as a replacement for the FIP limit.

EPA has previously approved Ohio's rule for other sources in Sandusky County. The amended rule updates the names of three companies and deletes one source from the rule but makes no substantive changes in the limits. EPA believes that the full rule is approvable.

C. Additional Substantive Rule Revisions

Two additional rules include substantive revisions to applicable limits. The first is for Auglaize County. The applicable attainment demonstration, approved on January 27, 1981 at 46 FR 8481, provides for emissions above the county's generic limit of 2.6 pounds per million BTU for several emission points at the Saint Mary's municipal power plant, but the previously approved rules only authorize emissions above that generic limit for one unit. Ohio amended its rules to replace a limit of 6.5 ι/MM Btu just for boiler number 6 with a limit of 5.9 ι/MM Btu applicable to both the number 6 and the number 5 boilers. The previously approved attainment demonstration demonstrates that these limits will provide for attainment, so these amendments are approvable.

For Cuyahoga County, Ohio amended its rules to incorporate an additional general emission limit. In the Cuyahoga County rules that EPA approved in January 2005, Ohio had generally amended the rules to match the federally promulgated rules for this county. In particular, Ohio adopted the federally promulgated generic limit for coal-fired boilers with greater than 350 MM Btu per hour heat input. However, the State had failed to adopt the federally promulgated generic limit for coal-fired boilers with heat input between 10 MM Btu and 350 MM Btu per hour. The rule submitted on May 16, 2006 adds this second generic limit that applies to smaller boilers. This limit is part of the plan that has been demonstrated to provide for attainment, and so the addition of this limit is approvable.

D. Rules With Only Name Changes or Other Administrative Changes

As a result of its periodic rule review, Ohio amended numerous rules to update company names, to correct various unit identifications, and to correct typographical errors. In addition to making these types of amendments in the rules discussed above, Ohio made these types of revisions to the rules for 34 additional counties. The counties for which Ohio submitted such rules are Allen, Ashtabula, Athens, Butler, Champaign, Clark, Erie, Fairfield, Geauga, Greene, Hamilton, Hancock, Lake Lawrence, Lorain, Lucas, Marion, Miami, Montgomery, Muskingum, Ottawa, Paulding, Pike, Richland, Ross, Scioto, Seneca, Shelby, Trumbull, Tuscarawas, Van Wert, Washington, Wayne, and Wood Counties.

Ohio amended two rules because a source had been addressed in an incorrect county's rules. Specifically, a facility owned by Archer Daniels Midland (formerly A.E. Staley) is located in Hancock County, not Seneca County, and so Ohio removed this facility's limits from the Seneca County rule (Rule 3745–18–80) and inserted the identical limits in the Hancock County rule (Rule 3745–18–38).

These various revisions do not affect the stringency of the SIP but do enhance the clarity of the applicability of these limits. Therefore, these revised rules are approvable.

E. Designation of Summit County

EPA published its initial designations on October 5, 1978, at 43 FR 46011. The designation for SO_2 for a portion of Summit County, Ohio, was litigated, with the result that the Court of Appeals for the Sixth Circuit remanded the designation to EPA for reconsideration. See *PPG Industries, Inc.* v. *Costle* 630 F2d 462 (6th Cir. 1980). EPA's original nonattainment designation was based in large part on dispersion modeling analyses indicating that attainment could not be assured without reductions in allowable emissions from sources in the county. Thus, the remand was accompanied by an injunction to reassess the modeling analyses and the adequacy of the emission limits to assure attainment. Although EPA has subsequently reestablished designations for some portions of the county, an important part of the county remains undesignated. Since this rulemaking addresses the court's request for EPA to reconsider the modeling analysis of limits necessary to assure attainment, Ohio requested that EPA also reestablish a designation for this area, in particular requesting that EPA designate the area attainment.

As discussed above, Ohio has requested approval of emission limits that match the limits of the FIP, i.e. limits which modeling underlying the FIP have demonstrated to provide for attainment. Therefore, no further review of the modeling underlying the State limits of 1979 is necessary, and EPA may proceed to establish a designation for the portion of Summit County that is presently undesignated.

Air quality monitoring data from 2003 to 2006 indicate that SO_2 concentrations in Summit County are well below the standards, generally about a third the level of the standards or less. For the 24-hour standard of 365 ug/m3 (commonly the controlling standard), the high second high value (i.e., after computing the second high value for each monitoring site for each year, the highest of these second high values) is 141 ug/m3. Compared to the annual standard of 80 ug/m3, the highest value is 24 ug/m3. Compared to the 3-hour standard of 1300 ug/m3, the high second high value is 382 ug/m3.

Modeling evidence also indicates that the relevant portion of Summit County is attaining the standard. EPA believes there are no companies within the undesignated area significantly violating their SO_2 emission limits. EPA has identified one facility elsewhere in Summit County as a high priority violator with excess SO_2 emissions. However, this facility is approximately 5 kilometers from the nearest edge of the undesignated area. Furthermore, whereas the attainment modeling for the undesignated part of Summit County reflects emissions from several significant sources, including Firestone Rubber (a Barberton facility of a division called Seiberling Tire and Rubber Company), Midwest Rubber Company, and Ohio Brass, these facilities have now shut down. Therefore, if the modeling underlying the attainment demonstration were redone with current actual emission rates replacing maximum allowable emissions, the results of this modeling would show that SO_2 concentrations in the undesignated area are well below the standard. Therefore, EPA believes that this area should be designated attainment. While EPA has not analyzed whether the excess emissions noted above might be causing violations of the air quality standards elsewhere in the county, EPA believes that any such violations will be resolved by its current enforcement action, so that no change in the attainment designation of the remainder of the county is warranted. Thus, in combination, EPA believes that all of Summit County should be designated as attaining the SO_2 standards.

Section 107(d)(3)(E) of the Clean Air Act describes several prerequisites for redesignation of areas from nonattainment to attainment. Because the relevant portion of Summit County is not designated nonattainment and in fact has no designation, these provisions of Section 107(d)(3)(E) are not germane here.

III. What Action Is EPA Taking?

EPA is proposing to approve 44 rules for SO_2 in Ohio, including 4 general rules, 4 county-specific rules that replace FIP rules, 2 county-specific rules that incorporate substantive changes in limits, and 34 county-specific rules that reflect only administrative changes such as updating company names. EPA is also proposing to establish an attainment designation for the portion of Summit County that is presently undesignated. For simplicity, EPA is proposing to combine the designations into a single designation for the entire county rather than have separate designations for four subdivisions of the county.

By this action, EPA is proposing that state rules would supersede the last remaining portions of the FIP that was promulgated in 1976 *et seq*. Therefore, the FIP may be removed from the CFR if and when EPA makes final the action proposed today. Even after the FIP is removed, EPA may continue to take enforcement action against violations of the FIP limits discovered to have occurred during the time the FIP was in effect.

Today's notice provides proposed revisions to the CFR to implement the actions proposed here. EPA is proposing to rescind the entirety of 40 CFR 52.1881(b) (including general provisions and county-specific limits) and of 40 CFR 52.1882 (providing FIP compliance schedules). Since EPA is proposing that Ohio has approvable rules for the entire State, EPA is proposing to rescind the sections of 40 CFR 52.1881(a) that identify counties for which EPA has taken no action or has disapproved the state's plan. EPA is proposing to replace the listing of counties having approved rules with a rule-by-rule listing of approved rules. EPA is proposing that the action concerning the designation of Summit County would establish a simplified, county-wide designation of attainment. Since EPA is proposing to address the court remand that has affected the designations for Summit County, EPA is proposing to rescind the footnotes that identify the effects of the remand. (EPA is also proposing to rescind the footnote that was inadvertently applied to the designation of Trumbull County.)

IV. What Should I Consider as I Prepare My Comments for EPA?

When submitting comments, remember to:

1. Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).

2. Follow directions—The EPA may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

3. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

4. Describe any assumptions and provide any technical information and/or data that you used.

5. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

6. Provide specific examples to illustrate your concerns, and suggest alternatives.

7. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

8. Make sure to submit your comments by the comment period deadline identified.

V. Statutory and Executive Order Reviews

Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, September 30, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget.

Paperwork Reduction Act

This proposed rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*.).

Regulatory Flexibility Act

This proposed action merely proposes to approve state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq*.).

Unfunded Mandates Reform Act

Because this rule proposes to approve pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Order 13132: Federalism

This action also does not have Federalism implications because it does not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely proposes to approve a state rule implementing a federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act.

Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This proposed rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

This proposed rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

Because it is not a ''significant regulatory action'' under Executive Order 12866 or a ''significant regulatory action,'' this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001).

National Technology Transfer Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), 15 U.S.C. 272, requires Federal agencies to use technical standards that are developed or adopted by voluntary consensus to carry out policy objectives, so long as such standards are not inconsistent with applicable law or otherwise impractical. In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Absent a prior existing requirement for the state to use voluntary consensus standards, EPA has no authority to disapprove a SIP submission for failure to use such standards, and it would thus be inconsistent with applicable law for EPA to use voluntary consensus standards in place of a program submission that otherwise satisfies the provisions of the Clean Air Act. Therefore, the requirements of section 12(d) of the NTTAA do not apply.

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Sulfur oxides.

40 CFR Part 81

Environmental protection, Air pollution control, National parks, Sulfur dioxide, Wilderness areas.

Dated: April 19, 2007.

Bharat Mathur,

Acting Regional Administrator, Region 5.

For the reasons stated in the preamble, parts 52 and 81, chapter I, of title 40 of the Code of Federal Regulations are proposed to be amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart KK—Ohio

2. Section 52.1870 is amended by adding paragraph (c)(136) to read as follows:

§ 52.1870 Identification of plan.

* * * * *

(c) * * *

(136) On May 16, 2006, Ohio submitted numerous regulations for sulfur dioxide. These regulations were submitted to replace the remaining federally promulgated regulations, to make selected revisions to applicable limits, and to update company names and make other similar administrative changes.

(i) *Incorporation by reference.* Ohio Administrative Code Rules 3745–18–01, 3745–18–02, 3745–18–03, 3745–18–06, 3745–18–08, 3745–18–10, 3745–18–11, 3745–18–12, 3745–18–15, 3745–18–17, 3745–18–18, 3745–18–24, 3745–18–28, 3745–18–29, 3745–18–31, 3745–18–34, 3745–18–35, 3745–18–37, 3745–18–38, 3745–18–49, 3745–18–50, 3745–18–53, 3745–18–54, 3745–18–57, 3745–18–61, 3745–18–63, 3745–18–66, 3745–18–68, 3745–18–69, 3745–18–72, 3745–18–76, 3745–18–77, 3745–18–78, 3745–18–79, 3745–18–80, 3745–18–81, 3745–18–82, 3745–18–83, 3745–18–84, 3745–18–85, 3745–18–87, 3745–18–90, 3745–18–91, and 3745–18–93, adopted on January 13, 2006, effective January 23, 2006.

(ii) *Additional material.* Letter from Joseph P. Koncelik, Director, Ohio EPA, to Bharat Mathur, EPA Region 5, dated May 16, 2006, with attachments providing supporting material.

3. Section 52.1881 is amended as follows:

a. By revising paragraph (a)(4).

b. By removing and reserving paragraphs (a)(7), (a)(8), and (b).

§ 52.1881 Control strategy: Sulfur oxides (sulfur dioxide).

(a) * * *

(4) Notwithstanding the portions of Ohio's sulfur dioxide rules identified in this section that EPA has either disapproved or taken no action on, EPA has approved a complete plan addressing all counties in the State of Ohio. EPA has approved the following rules, supplemented by any additional approved rules specified in 40 CFR 52.1870:

(i) Rules as effective in Ohio on December 28, 1979: OAC 3745–18–04 (measurement methods)—except for five disapproved paragraphs ((D)(2), (D)(3), (E)(2), (E)(3), and (E)(4)) and three paragraphs approved later ((D)(8), (D)(9), and (E)(7)), OAC 3745–18–05 (ambient monitoring), OAC 3745–18–08 (Allen)—except for one paragraph approved later (Cairo Chemical), OAC 3745–18–09 (Ashland County), OAC 3745–18–13 (Belmont), OAC 3745–18–14 (Brown), OAC 3745–18–16 (Carroll), OAC 3745–18–19 (Clermont)—except for one paragraph approved later (CG&E Beckjord), OAC 3745–18–20 (Clinton), OAC 3745–18–21 (Columbiana), OAC 3745–18–23 (Crawford), OAC 3745–18–25 (Darke), OAC 3745–18–26 (Defiance), OAC 3745–18–27 (Delaware), OAC 3745–18–30 (Fayette), OAC 3745–18–32 (Fulton), OAC 3745–18–36 (Guernsey), OAC 3745–18–39 (Hardin), OAC 3745–18–40 (Harrison), OAC 3745–18–41 (Henry), OAC 3745–18–42 (Highland), OAC 3745–18–43 (Hocking), OAC 3745–18–44 (Holmes), OAC 3745–18–45 (Huron), OAC 3745–18–46 (Jackson), OAC 3745–18–48 (Knox), OAC 3745–18–51 (Licking), OAC 3745–18–52 (Logan), OAC 3745–18–55 (Madison), OAC 3745–18–58 (Medina), OAC 3745–18–59 (Meigs), OAC 3745–18–60 (Mercer), OAC 3745–18–62 (Monroe), OAC 3745–18–64 (Morgan)—except for one paragraph approved later (OP Muskinghum River), OAC 3745–18–65 (Morrow), OAC 3745–18–67 (Noble), OAC 3745–18–70 (Perry), OAC 3745–18–73 (Portage), OAC 3745–18–74 (Preble), OAC 3745–18–75 (Putnam), OAC 3745–18–86 (Union), OAC 3745–18–88 (Vinton), OAC 3745–18–89 (Warren), OAC 3745–18–92 (Williams), and OAC 3745–18–94 (Wyandot);

(ii) Rules as effective in Ohio on October 1, 1982: OAC 3745–18–64 (B) (OP Muskinghum River in Morgan County);

(iii) Rules as effective in Ohio on October 31, 1991: OAC 3745–18–04 (D)(7), (D)(8)(a) to (D)(8)(e), (E)(5),

(E)(6)(a), (E)(6)(b), (F), (G)(1) to (G)(4), and (I);

(iv) Rules as effective in Ohio on July 25, 1996: OAC 3745–18–47 (Jefferson);

(v) Rules as effective in Ohio on March 21, 2006: OAC 3745–18–22 (Coshocton), OAC 3745–18–33 (Gallia), and OAC 3745–18–71 (Pickaway);

(vi) Rules as effective in Ohio on September 1, 2003: OAC 3745–18–56 (Mahoning); and

(vii) Rules as effective in Ohio on January 23, 2006: OAC 3745–18–01 (definitions), OAC 3745–18–02 (air quality standards), OAC 3745–18–03 (compliance dates), OAC 3745–18–06 (general provisions), OAC 3745–18–07 (Adams), OAC 3745–18–10 (Ashtabula), OAC 3745–18–11 (Athens), OAC 3745–18–12 (Auglaize), OAC 3745–18–15 (Butler), OAC 3745–18–17 (Champaign), OAC 3745–18–18 (Clark), OAC 3745–18–24 (Cuyahoga), OAC 3745–18–28 (Erie), OAC 3745–18–29 (Fairfield), OAC 3745–18–31 (Franklin), OAC 3745–18–34 (Geauga), OAC 3745–18–35 (Greene), OAC 3745–18–37 (Hamilton), OAC 3745–18–38 (Hancock), OAC 3745–18–49 (Lake), OAC 3745–18–50 (Lawrence), OAC 3745–18–53 (Lorain), OAC 3745–18–54 (Lucas), OAC 3745–18–57 (Marion), OAC 3745–18–61 (Miami), OAC 3745–18–63 (Montgomery), OAC 3745–18–66 (Muskingum), OAC 3745–18–68 (Ottawa), OAC 3745–18–69 (Paulding), OAC 3745–18–72 (Pike), OAC 3745–18–76 (Richland), OAC 3745–18–77 (Ross), OAC 3745–18–78 (Sandusky), OAC 3745–18–79 (Scioto), OAC 3745–18–80 (Seneca), OAC 3745–18–81 (Shelby), OAC 3745–18–82 (Stark), OAC 3745–18–83 (Summit), OAC 3745–18–84 (Trumbull), OAC 3745–18–85 (Tuscarawas), OAC 3745–18–87 (Van Wert), OAC 3745–18–90 (Washington), OAC 3745–18–91 (Wayne), and OAC 3745–18–93 (Wood).

* * * * *

§ 52.1882 [Removed]

4. Section 52.1882 is removed and reserved.

PART 81—[AMENDED]

5. The authority citation for part 81 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart C—Section 107 Attainment Status Designations

6. The table in § 81.336 entitled ''Ohio—SO_2'' is amended by removing the three footnotes and revising the entries for Summit and Trumbull Counties to read as follows:

§ 81.336 Ohio.

* * * * *

OHIO—SO_2

Designated area	Does not meet primary standards	Does not meet secondary standards	Cannot be classified	Better than national standards
		* * * * * * *		
Summit County				X
Trumbull County				X
		* * * * * * *		

[FR Doc. E7–8295 Filed 4–30–07; 8:45 am]

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Federal Register

Tuesday,
May 1, 2007

Part III

Environmental Protection Agency

40 CFR Part 141

Drinking Water: Regulatory Determinations Regarding Contaminants on the Second Drinking Water Contaminant Candidate List—Preliminary Determinations; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 141

[EPA–HQ–OW–2007–0068 FRL–8301–3]

RIN 2040–AE58

Drinking Water: Regulatory Determinations Regarding Contaminants on the Second Drinking Water Contaminant Candidate List—Preliminary Determinations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Safe Drinking Water Act (SDWA), as amended in 1996, requires the Environmental Protection Agency (EPA) to make regulatory determinations on at least five unregulated contaminants and decide whether to regulate these contaminants with a national primary drinking water regulation (NPDWR). SDWA requires that these determinations be made every five years. These unregulated contaminants are typically chosen from a list known as the Contaminant Candidate List (CCL), which SDWA requires the Agency to publish every five years. EPA published the second CCL (CCL 2) in the **Federal Register** on February 24, 2005 (70 FR 9071 (USEPA, 2005a)). This action presents the preliminary regulatory determinations for 11 of the 51 contaminants listed on CCL 2 and describes the supporting rationale for each. The preliminary determination is that an NPDWR is not appropriate for any of the 11 contaminants considered for regulatory determinations. The Agency seeks comment on these 11 preliminary determinations. While the Agency has not made a preliminary determination for perchlorate, this action provides an update on the Agency's evaluation of perchlorate. The Agency requests public comment on the information and the options that the Agency is considering in evaluating perchlorate and welcomes the submission of relevant, new information and/or data that may assist the Agency in its regulatory determination.

DATES: Comments must be received on or before July 2, 2007.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OW–2007–0068, by one of the following methods:

<bullet≤ *http://www.regulations.gov:* Follow the online instructions for submitting comments.

<bullet≤ *Mail:* Water Docket, Environmental Protection Agency, Mailcode: 2822T, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

<bullet≤ *Hand Delivery:* Water Docket, EPA Docket Center (EPA/DC). Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OW–2007–0068. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov.* The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional instructions on submitting comments, go to Unit I.B of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the Water Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the EPA Docket Center is (202) 566–2426.

FOR FURTHER INFORMATION CONTACT: Wynne Miller, Office of Ground Water and Drinking Water, Standards and Risk Management Division, at (202) 564–4887 or e-mail *miller.wynne@epa.gov.* For general information contact the EPA Safe Drinking Water Hotline at (800) 426–4791 or e-mail: *hotline-sdwa@epa.gov.*

SUPPLEMENTARY INFORMATION:

Abbreviations and Acronyms

a. i.—active ingredient
<—less than
<=—less than or equal to
≤—greater than
≤=—greater than or equal to
[mu]—microgram, one-millionth of a gram
[mu]g/g—micrograms per gram
[mu]g/kg—micrograms per kilogram
[mu]g/L—micrograms per liter
ATSDR—Agency for Toxic Substances and Disease Registry
AWWARF—American Water Works Association Research Foundation
BMD—bench mark dose
BMDL—bench mark dose level
BW—body weight for an adult, assumed to be 70 kilograms (kg)
CASRN—Chemical Abstract Services Registry Number
CBI—confidential business information
CDC—Centers for Disease Control and Prevention
ChE—cholinesterase
CCL—Contaminant Candidate List
CCL 1—EPA's First Contaminant Candidate List
CCL 2—EPA's Second Contaminant Candidate List
CFR—Code of Federal Regulations
CMR—Chemical Monitoring Reform
CWS—community water system
1,3-DCP—1,3-dichloropropene
DCPA—dimethyl tetrachloroterephthalate (dacthal)
DDE—1,1-dichloro-2,2-bis(p-chlorophenyl)ethylene
DDT—1,1,1-trichloro-2,2-bis(p-chlorophenyl)ethane
DNT—dinitrotoluene
DW—dry weight
DWEL—drinking water equivalent level
DWI—drinking water intake, assumed to be 2 L/day
EPA—United States Environmental Protection Agency
EPCRA—Emergency Planning and Community Right-to-Know Act
EPTC—s-ethyl dipropylthiocarbamate
ESA—ethane sulfonic acid
FDA—United States Food and Drug Administration
FQPA—Food Quality Protection Act
FR—Federal Register
FW—fresh weight
g—gram
g/day—grams per day

HRL—health reference level
IOC—inorganic compound
IRIS—Integrated Risk Information System
kg—kilogram
L—liter
LD_{50}—an estimate of a single dose that is expected to cause the death of 50 percent of the exposed animals; it is derived from experimental data.
LOAEL—lowest-observed-adverse-effect level
MAC—*mycobacterium avium intercellulare*
MCL—maximum contaminant level
MCLG—maximum contaminant level goal
mg—milligram, one-thousandth of a gram
mg/kg—milligrams per kilogram body weight
mg/kg/day—milligrams per kilogram body weight per day
mg/L—milligrams per liter
mg/m^3—milligrams per cubic meter
MRL—minimum or method reporting limit (depending on the study or suvey cited)
MTBE—methyl tertiary butyl ether
MTP—monomethyl-2,3,5,6-tetrachloroterephthalate
N—number of samples
NAS—National Academies of Sciences
NAWQA—National Water Quality Assessment (USGS Program)
NCEH—National Center for Environmental Health (CDC)
NCFAP—National Center for Food and Agricultural Policy
NCI—National Cancer Institute
NCWS—non community water system
ND—not detected (or non detect)
NDWAC—National Drinking Water Advisory Council
NHANES—National Health and Nutrition Examination Survey (CDC)
NIRS—National Inorganic and Radionuclide Survey
NIS—sodium iodide symporter
NOEL—no-observed-effect-level
NOAEL—no-observed-adverse-effect level
NPS—National Pesticide Survey
NQ—not quantifiable (or non quantifiable)
NRC—National Research Council
NPDWR—National Primary Drinking Water Regulation
NTP—National Toxicology Program
OA—oxanilic acid
OW—Office of Water
OPP—Office of Pesticide Programs
PCR—Polymerase Chain Reaction
PGWDB—pesticides in ground water data base
PWS—public water system
RED—Reregistration Eligibility Decision
RfC—reference concentration
RfD—reference dose
RSC—relative source contribution
SAB—Science Advisory Board
SDWA—Safe Drinking Water Act
SOC—synthetic organic compound
SVOC—semi-volatile organic compound
T3—triiodothyronine
T4—thyroxine
TDS—Total Diet Study (FDA)
Tg-DNT—technical grade DNT
TPA—2,3,5,6-tetrachchloroterephthalic acid
TRI—Toxics Release Inventory
TSH—thyroid stimulating hormone
TT—treatment technique
UCM—Unregulated Contaminant Monitoring
UCMR 1—First Unregulated Contaminant Monitoring Regulation
UF—uncertainty factor
US—United States of America
USDA—United States Department of Agriculture
USGS—United States Geological Survey
UST—underground storage tanks
VOC—volatile organic compound

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I. General Information

A. Does This Action Impose Any Requirements on My Public Water System?

None of these preliminary regulatory determinations or the final regulatory determinations, when published, will impose any requirements on anyone. Instead, this action notifies interested parties of the availability of EPA's preliminary regulatory determinations for 11 of the 51 contaminants listed on CCL 2 and seeks comment on these preliminary determinations. This action also provides an update on the Agency's review of perchlorate and methyl tertiary butyl ether (MTBE).

B. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at your estimate.

5. Provide specific examples to illustrate your concerns.

6. Offer alternatives.

7. Make sure to submit your comments by the comment period deadline.

8. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your response. It would also be helpful if you provided the name, date, and **Federal Register** citation related to your comments.

II. Purpose, Background and Summary of This Action

This section briefly summarizes the purpose of this action, the statutory requirements, previous activities related to the Contaminant Candidate List and regulatory determinations, and the approach used and outcome of these preliminary regulatory determinations.

A. What Is the Purpose of This Action?

The Safe Drinking Water Act (SDWA), as amended in 1996, requires EPA to publish a list of currently unregulated contaminants that may pose risks for drinking water (referred to as the Contaminant Candidate List, or CCL) and to make determinations on whether to regulate at least five contaminants from the CCL with a national primary drinking water regulation (NPDWR)

(section 1412(b)(1)). The 1996 SDWA requires the Agency to publish both the CCL and the regulatory determinations every five years. The purpose of this action is to present (1) EPA's preliminary regulatory determinations for 11 candidates selected from the 51 contaminants listed on the second CCL (CCL 2), (2) the process and the rationale used to make these determinations, and (3) a brief summary of the supporting documentation. This action also includes a request for comment(s) on the Agency's preliminary determinations.

The 11 regulatory determination contaminants candidates discussed in this action are boron, the dacthal mono- and di-acid degradates, 1,1-dichloro-2,2-bis(p-chlorophenyl)ethylene (DDE), 1,3-dichloropropene, 2,4-dinitrotoluene, 2,6-dinitrotoluene, s-ethyl propylthiocarbamate (EPTC), fonofos, terbacil, and 1,1,2,2-tetrachloroethane.

B. Background on the CCL and Regulatory Determinations

1. Statutory Requirements for CCL and Regulatory Determinations. The specific statutory requirements for the CCL and regulatory determinations can be found in SDWA section 1412(b)(1). The 1996 SDWA Amendments require EPA to publish the CCL every five years. The CCL is a list of contaminants that are not subject to any proposed or promulgated NPDWRs, are known or anticipated to occur in public water systems (PWSs), and may require regulation under SDWA. The 1996 SDWA Amendments also direct EPA to determine whether to regulate at least five contaminants from the CCL every five years (within three and one-half years after publication of the final list). In making regulatory determinations, SDWA requires EPA to publish a Maximum Contaminant Level Goal [1] (MCLG) and promulgate an NPDWR [2] for a contaminant if the Administrator determines that:

(a) The contaminant may have an adverse effect on the health of persons;

(b) the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and

(c) In the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

If EPA determines that all three of these statutory criteria are met and makes a final determination that a national primary drinking water regulation is needed, the Agency has 24 months to publish a proposed MCLG and NPDWR. After the proposal, the Agency has 18 months to publish and promulgate a final MCLG and NPDWR (SDWA section 1412(b)(1)(E)).[3]

2. The First Contaminant Candidate List (CCL 1). Following the 1996 SDWA Amendments, EPA sought input from the National Drinking Water Advisory Council (NDWAC) on the process that should be used to identify contaminants for inclusion on the CCL. For chemical contaminants, the Agency developed screening and evaluation criteria based on recommendations from NDWAC. For microbiological contaminants, NDWAC recommended that the Agency seek external expertise to identify and select potential waterborne pathogens. As a result, the Agency convened a workshop of microbiologists and public health experts who developed criteria for screening and evaluation and subsequently developed an initial list of potential microbiological contaminants.

The first CCL process benefited from considerable input from the NDWAC, the scientific community, and the public through stakeholder meetings and the public comments received on the draft CCL published on October 6, 1997 (62 FR 52193 (USEPA, 1997a)). EPA published the final CCL, which contained 50 chemical and 10 microbiological contaminants, on March 2, 1998 (63 FR 10273 (USEPA, 1998a)). A more detailed discussion of how EPA developed CCL 1 can be found in the 1997 and the 1998 **Federal Register** notices (62 FR 52193 (USEPA, 1997a) and 63 FR 10273 (USEPA, 1998a)).

3. The Regulatory Determinations for CCL 1. EPA published its preliminary regulatory determinations for a subset of contaminants listed on CCL 1 on June 3, 2002 (67 FR 38222 (USEPA, 2002a)). The Agency published its final regulatory determinations on July 18, 2003 (68 FR 42898 (USEPA, 2003a)). EPA identified 9 contaminants from the 60 contaminants listed on CCL 1 that had sufficient data and information available to make regulatory determinations. The 9 contaminants were *Acanthamoeba*, aldrin, dieldrin, hexachlorobutadiene, manganese, metribuzin, naphthalene, sodium, and sulfate. The Agency determined that a national primary drinking water regulation was not necessary for any of these 9 contaminants. The Agency issued guidance on *Acanthamoeba* and health advisories for magnesium, sodium, and sulfate.

The decision-making process that EPA used to make its regulatory determinations for CCL 1 was based on substantial expert input and recommendations from different groups including stakeholders, the National Research Council (NRC) and NDWAC. In June 2002, EPA consulted with the Science Advisory Board (SAB) Drinking Water Committee and requested its review and comment on whether the protocol EPA developed, based on the NDWAC recommendations, was consistently applied and appropriately documented. SAB provided verbal feedback regarding the use of the NRC and NDWAC recommendations in EPA's decision criteria for making its regulatory determinations. SAB recommended that the Agency provide a transparent and clear explanation of the process for making regulatory determinations. The Agency took SAB's recommendation into consideration and further explained the CCL 1 regulatory determination evaluation process in the July 18, 2003 (68 FR 42898 (USEPA, 2003a)) notice and in the supporting documentation.

EPA has used the same approach to develop the regulatory determinations discussed in this action. While this action includes a short description of the decision process used to make regulatory determinations (section II.C), a more detailed discussion can be found in the 2002 and the 2003 **Federal Register** notices (67 FR 38222 (USEPA, 2002a) and 68 FR 42898 (USEPA, 2003a)).

4. The Second Contaminant Candidate List (CCL 2). The Agency published its draft CCL 2 **Federal Register** notice on April 2, 2004 (69 FR 17406 (USEPA, 2004a)) and the final CCL 2 **Federal Register** notice on February 24, 2005 (70 FR 9071 (USEPA, 2005a)). The CCL 2 carried forward the 51 remaining chemical and microbial contaminants that were listed on CCL 1.

5. The Regulatory Determinations for CCL 2. This current action discusses EPA's preliminary determinations for 11 of the 51 contaminants listed on the CCL 2.

[1] The MCLG is the ''maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, and which allows an adequate margin of safety. Maximum contaminant level goals are nonenforceable health goals'' (40 CFR 141.2).

[2] An NPDWR is a legally enforceable standard that applies to public water systems. An NPDWR sets a legal limit (called a maximum contaminant level or MCL) or specifies a certain treatment technique (TT) for public water systems for a specific contaminant or group of contaminants.

[3] The statute authorizes a nine month extension of this promulgation date.

C. Summary of the Approach Used To Identify and Evaluate Candidates for Regulatory Determination 2

Figure 1 provides a brief overview of the process EPA used to identify which CCL 2 contaminants are candidates for regulatory determinations and the SDWA statutory criteria considered in making the regulatory determinations.

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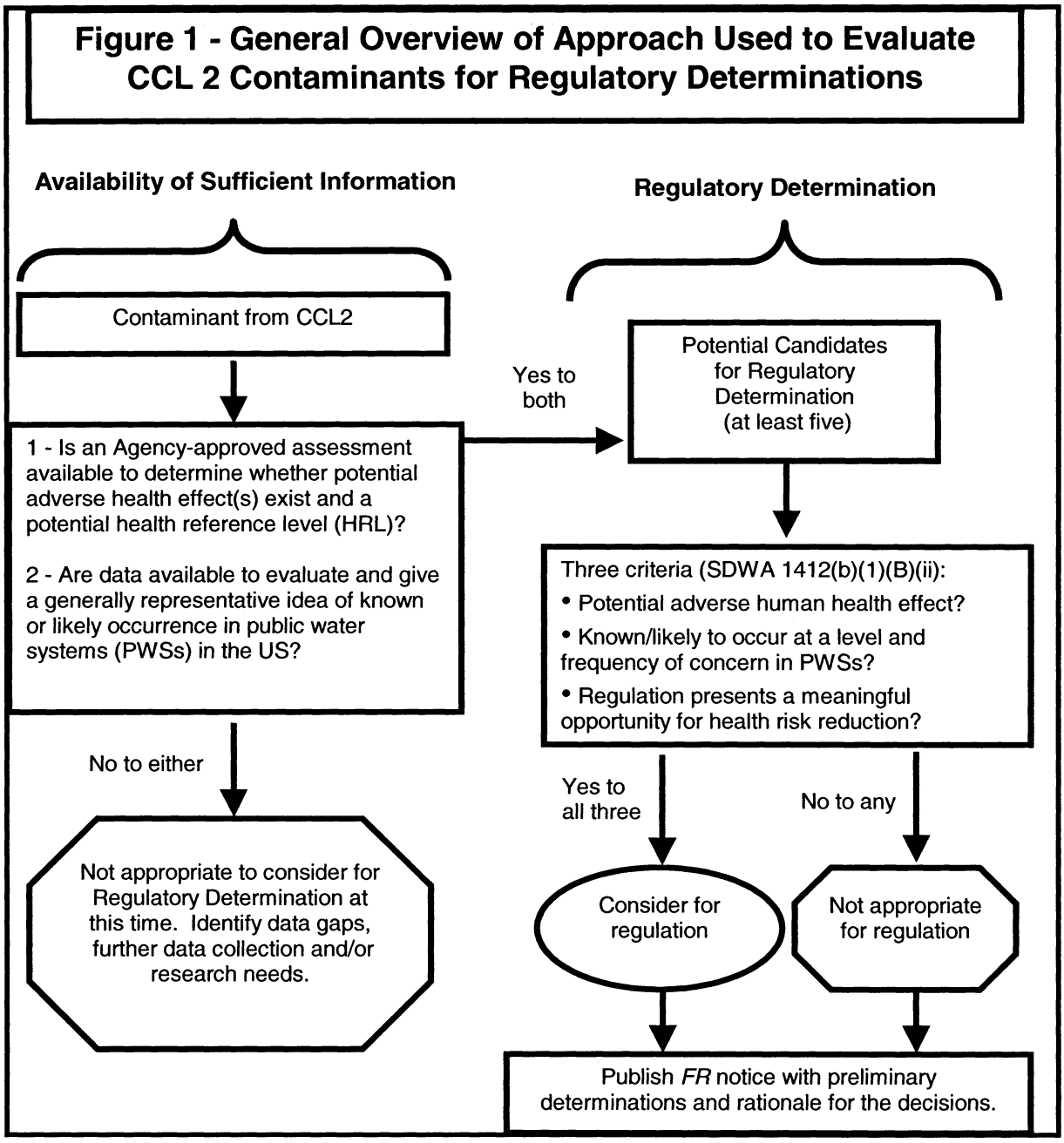

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In identifying which CCL 2 contaminants are candidates for regulatory determinations, the Agency considered whether sufficient information and/or data were available to characterize the potential health effects and the known/likely occurrence in and exposure from drinking water. With regards to sufficient health effects information/data, the Agency considered whether an Agency-approved health risk assessment [4] was available to identify any potential adverse health effect(s) and derive an estimated level at which adverse health effect(s) are likely to occur. With regards to sufficient occurrence information/data, the Agency considered whether information/data were available to

[4] Health information used for the regulatory determinations process includes but is not limited to health assessments available from the Agency's Integrated Risk Information System (IRIS), the Agency's Office of Pesticide Programs (OPP) in a Reregistration Eligibility Decision (RED), the National Academy of Sciences (NAS), and/or the Agency for Toxic Substances and Disease Registry (ATSDR).

evaluate and give a generally representative idea of known and/or likely occurrence in public water systems. If sufficient information/data were available to characterize adverse human health effects and known/likely occurrence in public water systems, the Agency identified the contaminant as a potential candidate for regulatory determinations. In addition to information/data for health and occurrence, EPA also considered the availability and adequacy of analytical methods (for monitoring) and treatment.

If EPA chose a contaminant as a candidate for regulatory determination, the Agency used an approach similar to the first regulatory determination process to answer the three statutory criteria (listed in section II.B.1).

For the current regulatory determination process, the Agency considered the following in evaluating each of the three statutory criteria.

(1) First statutory criterion—Is the contaminant likely to cause an adverse effect on the health of persons? The Agency evaluated the best available, peer-reviewed assessments and studies to characterize the human health effects that may result from exposure to the contaminant when found in drinking water. Based on this characterization, the Agency estimated a health reference level (HRL) for each contaminant. Section III.A provides more detailed information about the approach used to evaluate and analyze the health information.

(2) Second statutory criterion—Is the contaminant known or likely to occur in public water systems at a frequency and level of concern? To evaluate known occurrence in PWSs, the Agency compiled, screened, and analyzed data from several occurrence data sets to develop representative occurrence estimates for public drinking water systems. EPA used the HRL estimates for each contaminant as a benchmark against which to conduct an initial evaluation or screening of the occurrence data. For each contaminant, EPA estimated the number of PWSs (and the population served by these PWSs) with detections greater than one-half the HRL (≤ 1/2 HRL) and greater than the HRL (≤ HRL). To evaluate the likelihood of a contaminant to occur in drinking water, the Agency considered information on the use and release of a contaminant into the environment and supplemental information on occurrence in water (*e.g.*, ambient water quality data, State ambient or finished water data, and/or special studies performed by other agencies, organizations and/or entities). Section III.B provides more details on the approach used to analyze the occurrence information/data.

(3) Third statutory criterion—In the sole judgment of the Administrator, does regulation of the contaminant present a meaningful opportunity for health risk reduction for persons served by public water systems? EPA evaluated the potential health effects and the results of the occurrence and exposure estimates (i.e., the population exposed and the sources of exposure) at the health level of concern to determine if regulation presents a meaningful opportunity for health risk reduction. EPA has made a preliminary determination regarding the meaningful opportunity for health risk reduction for 11 contaminants based upon the population exposed to these contaminants at levels of concern.

If the answers to all three statutory criteria are affirmative for a particular contaminant, then the Agency makes a determination that a national drinking water regulation is necessary and proceeds to develop an MCLG and a national primary drinking water regulation for that contaminant. It should be noted that this regulatory determination process is independent of the more detailed analyses needed to develop a national primary drinking water regulation. Thus, a decision to regulate is the beginning of the Agency regulatory development process, not the end.

If the answer to any of the three statutory criteria is negative, then the Agency makes a determination that a national drinking water regulation is not necessary for that contaminant.

D. What Are EPA's Preliminary Determinations and What Happens Next?

EPA has made preliminary determinations that no regulatory actions are appropriate for the 11 contaminants evaluated for this second round of regulatory determinations. EPA will make final determinations on these 11 contaminants after a 60-day comment period. EPA is making preliminary regulatory determinations only on those CCL 2 contaminants that have sufficient information to support such a determination at this time. The Agency continues to conduct research and/or to collect information on the remaining CCL 2 contaminants to fill identified data gaps. The Agency is not precluded from taking action when information becomes available and will not necessarily wait until the end of the next regulatory determination cycle before making other regulatory determinations.

E. Supporting Documentation for EPA's Preliminary Determinations

For this action, EPA prepared several support documents that are available for review and comment in the EPA Water Docket and at *http://www.regulations.gov*. These support documents include:

<bullet≤ A comprehensive regulatory support document entitled, ''Regulatory Determinations Support Document for Selected Contaminants from the Second Drinking Water Contaminant Candidate List'' (CCL 2) (USEPA, 2006a). This support document summarizes the information and data on the physical and chemical properties, uses and environmental release, environmental fate, potential health effects, occurrence and exposure estimates, the preliminary determination for each contaminant candidate, and the Agency's rationale for its determination. The technical health and occurrence support documents listed next served as the basis for the health information and the drinking water occurrence estimates summarized in this comprehensive regulatory support document.

<bullet≤ Technical health support documents. These documents address exposure from drinking water and other media, toxicokinetics, hazard identification, and dose-response assessment, and provide an overall characterization of the risk from drinking water for the contaminants considered for regulatory determination. These documents are listed in the reference section as ''USEPA, 2006j'' through ''USEPA, 2006r.''

<bullet≤ Technical occurrence support documents (USEPA, 2006b and USEPA, 2006c). These documents include more detailed information about the sources of the data, how EPA assessed the data quality, completeness, and representativeness, and how the data were used to generate estimates of drinking water contaminant occurrence in support of these regulatory determinations. Section III.B.3 provides more information about the title and content of these technical support documents.

III. What Analyses Did EPA Use To Support the Preliminary Regulatory Determinations?

Sections III.A and B of this action outline the health effects and occurrence/exposure evaluation process EPA used to support these preliminary determinations.

A. Evaluation of Adverse Health Effects

Section 1412(b)(1)(A)(i) of SDWA requires EPA to determine whether each

candidate contaminant may have an adverse effect on public health. This section describes the overall process the Agency used to evaluate health effects information, the approach used to estimate a contaminant HRL (a benchmark against which to conduct the initial evaluation of the occurrence data), and the approach used to identify and evaluate information on hazard and dose-response for the contaminants under consideration. More specific information about the potential for adverse health effects for each contaminant is presented in section IV.B of this action.

There are two different approaches to the derivation of an HRL. One approach is used for chemicals that cause cancer and exhibit a linear response to dose and the other applies to noncarcinogens and carcinogens evaluated using a non-linear approach.

1. Use of Carcinogenicity Data for the Derivation of a Health Reference Level. For those contaminants considered to be likely or probable human carcinogens, EPA evaluated data on the mode of action of the chemical to determine the method of low dose extrapolation. When this analysis indicates that a linear low dose extrapolation is appropriate or when data on the mode of action are lacking, EPA uses a low dose linear extrapolation to calculate risk-specific doses. The risk-specific doses are the estimated oral exposures associated with lifetime excess risk levels that range from one cancer in ten thousand (10^{-4}) to one cancer in a million (10^{-6}). The risk-specific doses (expressed as mg/kg of body weight per day) are combined with adult body weight and drinking water consumption data to estimate drinking water concentrations corresponding to this risk range. EPA generally used the one-in-a-million (10^{-6}) cancer risk in the initial screening of the occurrence data for carcinogens evaluated using linear low dose extrapolation. Five of the eleven contaminants discussed in this action had data available to classify them as likely or probable human carcinogens. These five are also the only contaminants for which low dose linear extrapolations were performed. These five are p,p-dichlorodiphenyldichloroethylene (DDE), 1,3-dichloropropene (1,3-DCP or Telone), 2,4-dinitrotoluene, 2,6-dinitrotoluene, and 1,1,2,2-tetrachloroethane. The remaining 6 contaminants have not been identified as known, likely or probable carcinogens.

2. Use of Non-carcinogenic Health Effects Data for Derivation of an HRL. For those chemicals not considered to be carcinogenic to humans, EPA generally calculates a reference dose (RfD). A RfD is an estimate of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived from either a ''no-observed-adverse-effect level'' (NOAEL), a ''lowest-observed-adverse-effect level'' (LOAEL), or a benchmark dose, with uncertainty factors applied to reflect limitations of the data used.

The Agency uses uncertainty factors (UFs) to address uncertainty resulting from incompleteness of the toxicological database. The individual UFs (usually applied as integers of 1, 3, or 10) are multiplied together and used to derive the RfD from experimental data. Individual UFs are intended to account for:

(1) The variation in sensitivity among the members of the human population (*i.e.*, intraspecies variability);

(2) the uncertainty in extrapolating animal data to humans (*i.e.*, interspecies variability);

(3) the uncertainty in extrapolating from data obtained in a study with less-than-lifetime exposure to lifetime exposure (*i.e.*, extrapolating from subchronic to chronic exposure);

(4) the uncertainty in extrapolating from a LOAEL rather than from a NOAEL; and/or

(5) the uncertainty associated with an incomplete database.

For boron, the dacthal (DCPA) mono and di acid degradates, s-ethyl dipropylthiocarbamate (EPTC), fonofos and terbacil, EPA derived the HRLs using the RfD approach as follows:

HRL = [(RfD x BW)/DWI] x RSC

Where:

RfD = Reference Dose

BW = Body Weight for an adult, assumed to be 70 kilograms (kg)

DWI = Drinking Water Intake, assumed to be 2 L/day (90th percentile)

RSC = Relative Source Contribution, or the level of exposure believed to result from drinking water when compared to other sources (*e.g.*, food, ambient air). A 20 percent RSC is being used to estimate the HRL and screen the occurrence data because it is the lowest and most conservative RSC used in the derivation of an MCLG for drinking water. For each of the 6 aforementioned non-carcinogenic compounds for which the Agency has made a preliminary regulatory determination in this action, EPA used the RfD in conjunction with a 20 percent RSC to derive a conservative HRL estimate and perform an initial screening of the drinking water occurrence data. Since the initial screening of the occurrence data at this conservative HRL value resulted in a preliminary negative determination for each of these 6 compounds, the Agency determined that it was not necessary to further evaluate the RSC in making the regulatory determination.

As discussed in section IV.B.2 and 3, the HRL for the two dacthal degradates is based on the HRL value derived for the DCPA parent following the guidance provided by EPA's Office of Pesticide Programs.

3. Sources of Data/Information for Health Effects. EPA used the best available peer-reviewed data and analyses in evaluating adverse health effects. Peer-reviewed health-risk assessments were available for all chemicals considered for regulatory determinations from the Agency's Integrated Risk Information System (IRIS) Program[5] and/or the Office of Pesticide Programs (OPP) Reregistration Eligibility Decisions (RED).[6] Table 1 summarizes the sources of the health assessment data for each chemical under regulatory determination consideration. The Agency performed a literature search for studies published after the IRIS or OPP health-risk assessment was completed to determine if new information suggested a different outcome. The Agency collected and evaluated any peer-reviewed publications identified through the literature search for their impact on the RfD and/or cancer assessment. In cases where the recent data indicated that a change to the existing RfD or cancer assessment was needed, the updated OW assessment, as described in the health effects support document, was independently peer-reviewed. All quantitative cancer assessments conducted under the Guidelines for Carcinogen Risk Assessment (51 FR 33992 (USEPA, 1986)) were updated using the Guidelines for Carcinogen Risk Assessment (USEPA, 1999a) as directed in the November 2001 (66 FR 59593 (USEPA, 2001a)) **Federal Register** notice.

In March 2005, EPA updated and finalized the Cancer Guidelines and a Supplementary Children's Guidance,

[5] IRIS is an electronic EPA database (*http://www.epa.gov/iris/index.html*) containing peer-reviewed information on human health effects that may result from exposure to various chemicals in the environment. These chemical files contain descriptive and quantitative information on hazard identification and dose response, RfDs for chronic noncarcinogenic health effects, as well as slope factors and unit risks for carcinogenic effects.

[6] The OPP is required under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) to review all pesticides registered prior to 1984 and determine whether to reregister them for continued use. The results of the reregistration analysis are included in the REDs. Copies of the REDs are located at the following Web site: *http://cfpub.epa.gov/oppref/rereg/status.cfm?show=rereg.*

which include new considerations for mode of action and added guidelines related to potential risks due to early childhood exposure (USEPA, 2005b; USEPA, 2005c). EPA updated the earlier assessments (based on the 1986 Guidelines) for DDE, the dinitrotoluenes (2,4 and 2,6 as a mixture), and 1,1,2,2-tetrachloroethane following the 1999 Guidelines. None of these chemicals have been determined to have a mutagenic mode of action, which would require an extra factor of safety for children's health protection. Therefore, conducting the cancer evaluation using the 2005 Cancer Guidelines would not result in any change from the assessment updated following the 1999 Guidelines.

The cancer assessment for 1,3-dichloropropene was done by OPP and IRIS (USEPA, 1998b and 2000a) under the Proposed Guidelines for Carcinogen Risk Assessment (61 FR 17960 (USEPA, 1996a)). The Administrator (USEPA, 2005d) has directed that current completed assessments can be considered to be scientifically sound based on the guidance used when the assessment was completed until a new assessment is performed by one of the responsible program offices.

TABLE 1.—SOURCES AND DATES OF EPA HEALTH RISK ASSESSMENTS

Chemical	IRIS	Date	OPP RED	Date
Boron	X	2004	.....	.....
Dacthal and its mono- and di-acid degradates	X	1994	X	1998
1,3-Dichloropropene	X	2000	X	1998
DDE	X	1988	.....	.....
2,4-Dinitrotoluene	X	1990/1992	.....	.....
2,6-Dinitrotoluene	* X	1990	.....	.....
EPTC	X	1990	X	1999
Fonofos	X	1991	** X	1996
Terbacil	X	1989	X	1998
1,1,2,2-Tetrachloroethane	X	1986	.....	.....

* Applies to a mixture of 98 percent 2,4-dinitrotoluene and 2 percent 2,6-dinitrotoluene.
** Health Risk Assessment; RED not completed due to pesticide cancellation.

As noted in section II.E, EPA has prepared several technical health effects support documents for the contaminants considered for this round of regulatory determinations. These documents address the exposure from drinking water and other media, toxicokinetics, hazard identification, and dose-response assessment, and provide an overall characterization of risk from drinking water.

B. Evaluation of Contaminant Occurrence and Exposure

EPA used data from several sources to evaluate occurrence and exposure for the 11 contaminants considered in these regulatory determinations. The major or primary sources of the drinking water occurrence data used to support these determinations include the following sources:

<bullet≤ The first Unregulated Contaminant Monitoring Regulation (UCMR 1),

<bullet≤ The Unregulated Contaminant Monitoring (UCM) program, and

<bullet≤ The National Inorganic and Radionuclide Survey (NIRS).

In addition to these primary sources of occurrence data, the Agency also evaluated supplemental sources of occurrence information. Section III.B.1 of this action provides a brief summary of the primary sources of drinking water occurrence data and section III.B.2 provides brief summary descriptions of the supplemental sources of occurrence information and/or data. A summary of the occurrence data and the results or findings for each of the 11 contaminants considered for regulatory determination is presented in Section IV.B, the contaminant profiles section.

1. Primary Data Sources. As previously mentioned, the primary sources of the drinking water occurrence data used to support this action are the UCMR 1, the UCM program, and NIRS. The following sections provide a brief summary of the data sources and the approach used to estimate a given contaminant's occurrence. Table 2 lists the primary data sources the Agency used for each of the 11 contaminants considered for regulatory determinations.

TABLE 2.—PRIMARY SOURCES OF DRINKING WATER OCCURRENCE DATA USED IN THE REGULATORY DETERMINATION PROCESS

Number	Contaminant	Primary data sources				
		UCMR 1		UCM		NIRS
		List 1 assessment monitoring	List 2 screening survey	Round 1 cross section	Round 2 cross section	
1	Boron					[1] X
2	Dacthal mono- and					
3	di-acid degradates	X				
4	DDE	X				
5	1,3-Dichloropropene	[2] X		X	X	
6	2,4-Dinitrotoluene	X				
7	2,6-Dinitrotoluene	X				
8	EPTC	X				
9	Fonofos		X			
10	Terbacil	X				

TABLE 2.—PRIMARY SOURCES OF DRINKING WATER OCCURRENCE DATA USED IN THE REGULATORY DETERMINATION PROCESS—Continued

Number	Contaminant	Primary data sources				
		UCMR 1		UCM		NIRS
		List 1 assessment monitoring	List 2 screening survey	Round 1 cross section	Round 2 cross section	
11	1,1,2,2-Tetrachloroethane			X	X	

[1] For boron, EPA also considered the results of a study funded by AWWARF (Frey *et al.*, 2004).
[2] 1,3-Dichloropropene was sampled as a UCM Round 1 and 2 analyte but due to sample degradation concerns the contaminant was re-analyzed using the samples provided by the small systems that participated in the UCMR 1 List 1 Assessment Monitoring.

a. *The Unregulated Contaminant Monitoring Regulation.* In 1999, EPA developed the UCMR program in coordination with the CCL and the National Drinking Water Contaminant Occurrence Database (NCOD) to provide national occurrence information on unregulated contaminants (September 17, 1999, 64 FR 50556 (USEPA, 1999b); March 2, 2000, 65 FR 11372 (USEPA, 2000b); and January 11, 2001, 66 FR 2273 (USEPA, 2001b)). EPA used data from the UCMR 1 program to evaluate occurrence for 9 of the 11 contaminants considered for these regulatory determinations. These 9 contaminants include the dacthal mono- and di-acid degradates, DDE, 1,3-dichloropropene, 2,4-dinitrotoluene, 2,6-dinitrotoluene, EPTC, fonofos, and terbacil.

EPA designed the UCMR 1 data collection with three parts (or tiers) primarily based on the availability of analytical methods. Occurrence data for 8 of the 9 contaminants listed in the preceding paragraph are from the first tier of UCMR (also known as UCMR 1 List 1 Assessment Monitoring). Occurrence data for fonofos are from the second tier of UCMR 1 (also known as the UCMR 1 List 2 Screening Survey). EPA has not collected data as part of the third tier due to the lack of adequate analytical methods.

The UCMR 1 List 1 Assessment Monitoring was performed for a specified number of chemical contaminants for which analytical methods have been developed. EPA required all large[7] PWSs, plus a statistically representative national sample of 800 small [8] PWSs to conduct Assessment Monitoring.[9] Approximately one-third of the participating small systems were scheduled to monitor for these contaminants during each calendar year from 2001 through 2003. Large systems could conduct one year of monitoring anytime during the 2001–2003 UCMR 1 period. EPA specified a quarterly monitoring schedule for surface water systems and a twice-a-year, six-month interval monitoring schedule for ground water systems. The objective of the UCMR 1 sampling approach for small systems was to collect contaminant occurrence data from a statistically selected, nationally representative sample of small systems. The small system sample was stratified and population-weighted, and included some other sampling adjustments such as allocating a selection of at least 2 systems from each State. With contaminant monitoring data from all large PWSs and a statistical, nationally representative sample of small PWSs, the UCMR 1 List 1 Assessment Monitoring program provides a contaminant occurrence data set suitable for national drinking water estimates.

In total, 370,312 sample results have been collected under the UCMR 1 List 1 Assessment Monitoring program at approximately 3,083 large systems and 797 small systems. Approximately 33,600 samples were collected for each contaminant. The UCMR 1 List 1 Monitoring program included systems from all 50 States, the District of Columbia, 4 U.S. Territories, and Tribal lands in 5 EPA Regions. An additional 3,719 samples were collected for 1,3-DCP at all small systems that conducted UCMR 1 List 1 Assessment Monitoring.

In addition to the UCMR 1 List 1 Assessment Monitoring, EPA required monitoring for selected contaminants (including fonofos) for which analytical methods were developed but not widely used. Known as the UCMR 1 List 2 Screening Survey, EPA randomly selected 300 public water systems (120 large and 180 small systems) from the pool of systems required to conduct UCMR 1 List 1 Assessment Monitoring. In total, 29,765 sample results have been collected under the UCMR 1 List 2 Screening Survey from the participating large and small systems. Approximately 2,300 samples were collected for each contaminant. The UCMR 1 List 2 Screening Survey included systems from 48 States, 2 U.S. Territories, and Tribal lands in 1 EPA Region. EPA used the occurrence data from this survey to evaluate fonofos.

EPA analyzed the UCMR 1 List 1 Assessment Monitoring and List 2 Screening Survey data to generate the following initial occurrence and exposure summary statistics:

<bullet≤ The total number of systems and the total population served by these systems,

<bullet≤ The number and percentage of systems with at least 1 observed detection that has a concentration greater than ½ the HRL and greater than the HRL (or in some cases greater than or equal to the minimum reporting limit or MRL), and

<bullet≤ The number of people and percentage of the population served by systems with at least one observed detection greater than ½ the HRL and greater than the HRL (or in some cases greater than or equal to the MRL).[10]

The initial UCMR 1 summary occurrence statistics for dacthal mono- and di-acid degradates, DDE, 1,3-dichloropropene, 2,4-dinitrotoluene, 2,6-dinitrotoluene, EPTC, fonofos, and terbacil are presented in section IV.B of this action.

b. *The Unregulated Contaminant Monitoring Program Rounds 1 and 2.* In 1987, EPA initiated the UCM program to fulfill a 1986 SDWA Amendment that required monitoring of specified unregulated contaminants to gather information on their occurrence in drinking water for future regulatory decision-making purposes. EPA used data from the UCM program to evaluate

[7] Systems serving more than 10,000 people.
[8] Systems serving 10,000 people or fewer.
[9] Large and small systems that purchase 100% of their water supply were not required to participate in the UCMR 1 Assessment Monitoring or the UCMR 1 Screening Survey.
[10] EPA's support documents (USEPA, 2006a and 2006b) provide summary statistics for the median and 99th percentile concentrations of all analytical detections and detailed occurrence results based on UCMR data according to source water type (surface versus ground water), system size, and State.

occurrence for 2 of the 11 contaminants considered for these regulatory determinations. These two contaminants are 1,3-dichloropropene and 1,1,2,2-tetrachloroethane.

EPA implemented the UCM program in two phases or rounds. The first round of UCM monitoring generally extended from 1988 to 1992 and is referred to as UCM Round 1 monitoring. The second round of UCM monitoring generally extended from 1993 to 1997 and is referred to as UCM Round 2 monitoring.

UCM Round 1 monitored for 34 volatile organic compounds (VOCs), including 1,3-dichloropropene and 1,1,2,2-tetrachloroethane (52 FR 25720 (USEPA, 1987)). UCM Round 2 monitored for 13 synthetic organic compounds (SOCs), sulfate and the same 34 VOCs from UCM Round 1 monitoring (57 FR 31776 (USEPA, 1992a)).

The UCM Round 1 database contains contaminant occurrence data from 38 States, Washington, DC, and the U.S. Virgin Islands. The UCM Round 2 database contains data from 34 States and several Tribes. Due to incomplete State data sets, national occurrence estimates based on raw (unedited) UCM Round 1 or Round 2 data could be skewed to low-occurrence or high-occurrence settings (e.g., some States only reported detections). To address potential biases in the data,[11] EPA developed national cross-sections from the UCM Round 1 and Round 2 State data using an approach similar to that used for EPA's 1999 Chemical Monitoring Reform (CMR), the first Six Year Review, and the first CCL Regulatory Determinations. This national cross-section approach was developed to support occurrence analyses and was supported by scientific peer reviewers and stakeholders. This approach identified 24 of the original 38 States from the UCM Round 1 database and 20 of the original 34 States from the UCM Round 2 data base for the national cross-section.

Because UCM Round 1 and Round 2 data represent different time periods and include occurrence data from different States, EPA developed separate national cross-sections for each data set. The UCM Round 1 national cross-section consists of data from 24 States, with approximately 3.3 million total analytical data points from approximately 22,000 unique PWSs. The UCM Round 2 national cross-section consists of data from 20 States, with approximately 3.7 million analytical data points from slightly more than 27,000 unique PWSs. The UCM Round 1 and 2 national cross-sections represent significantly large samples of national occurrence data. Within each cross-section, the actual number of systems and analytical records for each contaminant varies. The support document, ''The Analysis of Occurrence Data from the Unregulated Contaminant Monitoring (UCM) Program and National Inorganics and Radionuclides Survey (NIRS) in Support of Regulatory Determinations for the Second Drinking Water Contaminant Candidate List'' (USEPA, 2006c), provides a description of how the national cross-sections for the Round 1 and Round 2 data sets were developed.

EPA constructed the national cross-sections in a way that provides a balance and range of States with varying pollution potential indicators, a wide range of the geologic and hydrologic conditions, and a very large sample of monitoring data points. While EPA recognizes that some limitations exist, the Agency believes that the national cross-sections do provide a reasonable estimate of the overall distribution and the central tendency of contaminant occurrence across the United States.

EPA analyzed the UCM Round 1 and 2 National Cross-Section data to generate the following initial occurrence and exposure summary statistics:

<bullet≤ The total number of systems and the total population served by these systems,

<bullet≤ The number and percentage of systems with at least 1 observed detection that has a concentration greater than ½ the HRL and greater than the HRL (or in some cases greater than or equal to the MRL), and

<bullet≤ The number of people and percentage of the population served by systems with at least 1 observed detection that has a concentration greater than ½ the HRL and greater than the HRL (or in some cases greater than or equal to the MRL).[12]

The initial UCM summary occurrence statistics for 1,3-dichloropropene and 1,1,2,2-tetrachloroethane are presented in section IV.B of this action.

c. *National Inorganic and Radionuclide Survey.* In the mid-1980's, EPA conducted the NIRS to provide a statistically representative sample [13] of the national occurrence of inorganic contaminants in community water systems (CWSs) served by ground water. EPA used data from NIRS, as well as a supplemental survey, to evaluate occurrence for boron.

The NIRS database includes 36 radionuclides and inorganic compounds (IOCs), including boron. The NIRS provides contaminant occurrence data from 989 ground water CWSs covering 49 States (all except Hawaii) and does not include surface water systems. The survey focused on ground water systems, in part because IOCs tend to occur more frequently and at higher concentrations in ground water than in surface water. Each of the 989 randomly selected CWSs was sampled at a single time between 1984 and 1986.

EPA analyzed the NIRS data to generate the following occurrence and exposure summary statistics for boron:

<bullet≤ The total number of systems and the total population served by these systems,

<bullet≤ The number and the percentage of systems with at least 1 detection that has a concentration greater than ½ the HRL and greater than the HRL,

<bullet≤ The number of people and percentage of the population served by systems with at least 1 observed detection that has a concentration greater than ½ the HRL and greater than the HRL.[14]

Similar to the treatment of the UCM cross-section data, the actual values for the NIRS analyses of boron are reported in section IV.B. Because the NIRS data were collected in a randomly designed sample survey, these summary statistics are representative of national occurrence in ground water CWSs.

One limitation of the NIRS is a lack of occurrence data for surface water systems. To provide perspective on the occurrence of boron in surface water systems relative to ground water systems, EPA reviewed and took into consideration a recent boron occurrence survey funded by American Water Works Association Research Foundation (AWWARF) (Frey *et al.*, 2004). A short description of the AWWARF study is provided in the supplemental section

[11] The potential bias in the raw UCM data are due to lack of representativeness (since not all States provided UCM data) and incompleteness (since some States that provided data had incomplete data sets).

[12] EPA's support documents (USEPA, 2006a and 2006c) provide summary statistics for the median and 99th percentile concentrations of all analytical detections and detailed occurrence results based on the UCM Round 1 and 2 Nationals Cross-Sectons according to source water type (surface versus ground water), system size, and State.

[13] NIRS was designed to provide results that are statistically representative of natioal occurrence at CWSs using ground water sources and is stratified based on system size (population served by the system). Most of the NIRS data are from smaller systems (92 percent from systems serving 3,300 persons or fewer).

[14] EPA's support documents (USEPA, 2006a and 2006c) provide the number and percentage of systems with detections, the 99th percentile concentration of all samples, the 99th percentile concentration of samples with detections, and the median concentration of samples with detections.

(section III.B.2) and the results of the AWWARF survey are presented in section IV.B of this action.

d. *Presentation of Occurrence Data and Analytical Approach.* As noted previously, the occurrence values and summary statistics presented in this action are the actual data from the UCMR 1, UCM, and NIRS data sets. These occurrence values represent direct counts of the number and percent of systems, and population served by systems, with at least 1 analytical detection above some specified concentration threshold. EPA considered this to be the most straightforward and accurate way to present these data for the regulatory determination process.

While both UCMR 1 and UCM data could support more involved statistical modeling to characterize occurrence based on mean (rather than peak) concentrations, EPA chose not to perform this step for the regulatory determinations proposed in this action. EPA believes that presenting the actual results of the occurrence monitoring is straight-forward and the use of an analysis based on peak concentrations provides conservative estimates of occurrence and potential exposure from drinking water. Given that the preliminary determinations for the 11 contaminants discussed in this action are negative, it is not necessary to go beyond the conservative (peak concentration) approach used for this analysis.

2. Supplemental Data. The Agency evaluated several sources of supplemental occurrence information to augment the primary drinking water occurrence data, to evaluate the likelihood of contaminant occurrence, and/or to more fully characterize a contaminant's presence in the environment. Sections II.B.2.a through II.B.2.f provide brief descriptions of the main supplemental information/data sources cited in this action. Summarized occurrence findings from these supplemental sources are presented in Section IV.B, the contaminant profiles section. While the following descriptions cover the more commonly referenced supplemental sources of information/data, they do not include every study and survey cited in the contaminant discussions. A more detailed discussion of the supplemental sources of information/data that EPA evaluated for each contaminant can be found in the comprehensive regulatory determination support document (USEPA, 2006a).

a. *USGS NAWQA Information/Data.* The United States Geological Survey (USGS) collects long-term and nationally consistent data describing water quality in ground water and surface water. In 1991, USGS implemented the National Water-Quality Assessment (NAWQA) Program for 10-year cyclical data collection and data analyses. During the first cycle (1991–2001), the NAWQA program monitored 51 major watersheds and aquifers (study units), which supply more than 60% of the nation's drinking water and water used for agriculture and industry in the U.S. (Hamilton *et al.*, 2004). NAWQA has collected data from over 6,400 surface water and 7,000 ground water sampling points. USGS National Synthesis teams prepare comprehensive analyses of data on topics of particular concern. EPA evaluated information/data from the following USGS National Synthesis reports/projects:

(1) The NAWQA Pesticide National Synthesis Project. In 2003, USGS posted the preliminary results from the first cycle of monitoring for pesticides in streams and ground water. USGS considers these results to be provisional. The results and the data can be accessed at *http://ca.water.usgs.gov/pnsp/.* Data are presented separately for surface water and ground water, as well as bed sediments and biota. In each case, results are subdivided by land use category. Land use categories include agricultural, urban, mixed (deeper aquifers of regional extent in the case of ground water), and undeveloped. In this action, the NAWQA pesticide data for surface water are referenced as Martin *et al.* (2003) and the ground water data are referenced as Kolpin and Martin (2003).

(2) The National Survey of MTBE and Other VOCs in Community Drinking Water Sources (part of the VOC National Synthesis Project). In 2003, USGS published the survey findings for MTBE, other ether gasoline oxygenates, and other volatile organic compounds (VOCs) in source water used by CWSs in the United States. The survey was funded by AWWARF and performed by USGS in collaboration with the Metropolitan Water District of Southern California and the Oregon Health and Science University. USGS performed the survey in two independent stages designed to provide representative sampling of all CWSs in the United States (Random Source-Water Survey) and to improve understanding of the temporal variability of MTBE and other compounds in selected water sources (Focused Source-Water Survey). Participating water utilities provided samples that were analyzed for 66 VOCs. The random survey design selected 954 CWSs to be nationally representative of surface and ground waters sources used by CWSs. The focused survey studied source waters from 134 CWSs suspected or known to contain MTBE. The reports/results and data sets from the survey can be accessed at *http://sd.water.usgs.gov/nawqa/vocns/nat—survey.html.* The random survey results can be found in the USGS Water Resources Investigations Report 02–4079, referenced as Grady (2003). The focused survey results can be found in the USGS Water Resources Investigations Report 02–4084, referenced as Delzer and Ivahnenko (2003a).

b. *USGS National Highway Runoff Data and Methodology Synthesis.* In addition to the NAWQA project, USGS has prepared additional surveys of national contaminant occurrence. For the National Highway Runoff Data and Methodology Synthesis, USGS conducted a review of 44 studies of semi-volatile organic compounds (SVOCs) and VOCs in runoff conducted since 1970. The USGS Synthesis sought to evaluate data quality parameters for comparison between and among these studies, including documentation of sampling protocols and methods, limits of reporting and detection, and protocols of quality-control and quality-assurance. The complete USGS report is Open-File Report 98–409 and is referenced as Lopes and Dionne (1998).

c. *Toxics Release Inventory.* EPA established the Toxics Release Inventory (TRI) in 1987 in response to section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA). EPCRA section 313 requires facilities to report to both EPA and the States annual information on toxic chemical releases from facilities that meet reporting criteria. EPCRA section 313 also requires EPA to make this information available to the public through a computer database. This database is accessible through TRI Explorer, which can be accessed at *http://www.epa.gov/triexplorer*. In 1990 Congress passed the Pollution Prevention Act, which required that additional data on waste management and source reduction activities be reported under TRI. The TRI database details not only the types and quantities of toxic chemicals released to the air, water, and land by facilities, but also provides information on the quantities of chemicals sent to other facilities for further management (USEPA, 2002b and 2003b).

Facilities are required to report releases and other waste management activities related to TRI chemicals if they manufacture, process, or otherwise use more than established threshold quantities of these chemicals. Currently

for most chemicals, the thresholds are 25,000 pounds for manufacturing and processing and 10,000 pounds for use. Although TRI can provide a general idea of release trends, it is far from exhaustive and should not be used to estimate general public exposure to a chemical (USEPA, 2002b and 2003b).

d. *Pesticides in Ground Water Database.* The Pesticides in Ground Water Database (PGWDB) is a compilation of data from ground water studies conducted by Federal, State, and local governments, the pesticide industry, and other institutions between 1971 and 1991 (USEPA, 1992b). Data from 68,824 wells in 45 states are included. The vast majority of the wells (65,865) were drinking water wells. Monitoring was conducted for 258 pesticides and 45 degradates. Not all studies tested for every compound.

e. *The National Pesticide Survey.* In 1990, EPA completed a national survey of pesticides in drinking water wells. The purpose of the National Pesticide Survey (NPS) was to determine the national occurrence frequencies and concentrations of select pesticides in the nation's drinking water wells, and to improve EPA's understanding of how pesticide occurrence in ground water correlates with patterns of pesticide usage and ground water vulnerability. The survey included approximately 1,300 CWS wells and rural domestic wells. Sampling was conducted between 1988 and 1990. Wells were sampled for 101 pesticides, 25 pesticide degradates, and nitrate. The survey targeted areas representing a variety of pesticide usage levels and ground water vulnerability. The survey was designed to provide a statistically reliable estimate of pesticide occurrence in the nation's drinking water wells (USEPA, 1990a).

f. *The AWWARF Boron Study.* The American Water Works Research Foundation funded a survey to evaluate the occurrence of boron (as well as hexavalent chromium) in drinking water sources (Frey *et al.*, 2004). The AWWARF study recruited 189 PWSs representing 407 source waters in 41 states. Of the 407 source water sample kits distributed in 2003, approximately 342 were returned. Of these 342 samples, 341 were analyzed for boron. Approximately 67 percent (or 228) represented ground water sources and 33 percent (or 113) represented surface water sources. The results of the AWWARF survey for boron are presented in section IV.B of this action.

3. Supporting Documentation for Occurrence. As mentioned in section II.E, EPA prepared several technical occurrence documents to support this action. These technical occurrence documents include the following:

<bullet≤ ''The Analysis of Occurrence Data from the Unregulated Contaminant Monitoring (UCM) Program and National Inorganics and Radionuclides Survey (NIRS) in Support of Regulatory Determinations for the Second Drinking Water Contaminant Candidate List'' (USEPA, 2006c), which this action refers to as the ''UCM and NIRS Occurrence Report.''

<bullet≤ ''The Analysis of Occurrence Data from the First Unregulated Contaminant Monitoring Regulation (UCMR 1) in Support of Regulatory Determinations for the Second Drinking Water Contaminant Candidate List'' (USEPA, 2006b), which this action refers to as the ''UCMR 1 Occurrence Report.''

The ''UCM and NIRS Occurrence Report'' provides more detailed information about the UCM and the NIRS data, how EPA assessed the data quality, completeness, and representativeness, and how the data were used to generate estimates of contaminant occurrence. The ''UCMR 1 Occurrence Report'' provides more detailed information about the UCMR 1 data, how EPA assessed the data quality, completeness, representativeness, and how the data were used to generate estimates of contaminant occurrence.

The comprehensive regulatory support document (USEPA, 2006a) provides a summary of the results from the drinking water occurrence analyses discussed in the aforementioned technical support documents, as well as information on production and use, environmental releases, and/or occurrence in ambient water, potential health effects, the Agency's preliminary determination, and the rationale for the determination.

IV. Preliminary Regulatory Determinations

A. Summary of the Preliminary Regulatory Determination

The Agency has made a preliminary determination that each of the 11 contaminants listed in Table 3 do not meet all three of the SDWA criteria (discussed in section II.C) and thus do not warrant regulation with an NPDWR. Table 3 also summarizes the primary information used to make these regulatory determinations. Section IV.B of this action provides a more detailed summary of the information and the rationale used by the Agency to reach its preliminary decisions. The Agency solicits public comment on the preliminary determinations for these 11 contaminants.

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Table 3. Summary of the Health and Occurrence Information and the Preliminary Determinations for the 11 Contaminants Considered Under CCL Regulatory Determinations 2

#	Contaminant and Its Chemical Abstract Registry Number (CASRN)	Preliminary Determination	Health Reference Level (HRL)	Occurrence Findings from Primary Data Sources (UCMR 1, UCM Round 1 and 2 Cross Sections, NIRS)				
				Database	PWSs with at least 1 detection > ½ HRL	Population served by PWSs with at least 1 detection > ½ HRL	PWSs with at least 1 detection > HRL	Population served by PWSs with at least 1 detection > HRL
1	Boron (7440-42-8)	Do not regulate[1]	1,400 µg/L	NIRS	4.3% (43 of 989)	2.9% (42.7K of 1.48M)	1.7% or (17 of 989) [1]	0.4% (6.4K of 1.48M)
2 *3*	Dacthal di acid degradate[2] (2136-79-0) Dacthal mono acid degradate[3] (887-54-7)	Do not regulate	70 µg/L [4]	UCMR 1[5]	0.05% (2 of 3,868)	0.33% (739K of 225M)	0.03% (1 of 3,868)	<0.01% (500 of 225M)
4	DDE[6] (72-55-9)	Do not regulate	0.2 µg/L	UCMR 1	-------[7]	-------[7]	0.03%[7] (1 of 3,867) [8]	0.01% (18K of 226M) [8]
5	1,3-Dichloropropene (Telone) (542-75-6)	Do not regulate	0.4 µg/L	UCM Rd1 UCM Rd2 UCMR 1	0.16% (15 of 9,164) [9] 0.30% (50 of 16,787) [9] -------[7]	0.86% (436K of 51M) [9] 0.42% (193K of 46M) [9] -------[7]	0.16% (15 of 9,164) [9] 0.23% (38 of 16,787) [9] 0.00% (0 of 796) [8]	0.86% (436K of 51M) [9] 0.33% (152K of 46M) [9] 0.00% (0 of 2.8M) [8]
6	2,4-Dinitrotoluene (121-14-2)	Do not regulate	0.05 µg/L	UCMR 1	-------[7]	-------[7]	0.03% (1 of 3,866) [8]	0.02% (38K of 226M) [8]
7	2,6-Dinitrotoluene (606-20-2)	Do not regulate	0.05 µg/L	UCMR 1	-------[7]	-------[7]	0.00% (0 of 3,866) [8]	0.00% (0 of 226M) [8]
8	EPTC[10] (759-94-4)	Do not regulate	175 µg/L	UCMR 1	0.00% (0 of 3,866)	0.00% (0 of 226M)	0.00% (0 of 3,866)	0.00% (0 of 226M)
9	Fonofos (944-22-9)	Do not regulate	10 µg/L	UCMR 1	0.00% (0 of 295)	0.00% (0 of 41M)	0.00% (0 of 295)	0.00% (0 of 41M)
10	Terbacil (5902-51-2)	Do not regulate	90 µg/L	UCMR 1	0.00% (0 of 3,866)	0.00% (0 of 226M)	0.00% (0 of 3,866)	0.00% (0 of 226M)
11	1,1,2,2-Tetrachloroethane (79-34-5)	Do not regulate	0.4 µg/L	UCM Rd1 UCM Rd2	0.22% (44 of 20,407) [9] 0.07% (18 of 24,800) [9]	1.69% (1.6M of 95M) [9] 0.51% (362K of 71M) [9]	0.20% (41 of 20,407) [9] 0.07% (17 of 24,800) [9]	1.63% (1.5M of 95M) [9] 0.08% (56K of 71M) [9]

Footnotes: (1) EPA also considered the results of an AWWARF study of PWSs indicating that surface water sources are unlikely to contain boron at levels > the HRL of 1,400 µg/L (Frey *et al.*, 2004). (2) 2,3,5,6-tetrachchloroterephthalic acid (TPA). (3) monomethyl-2,3,5,6-tetrachloroterephthalate (MTP). (4) Using the dacthal parent HRL since it includes the toxicity for the degradates. (5) Degradates monitored in aggregate and converted to the parent equivalent. (6) 1,1-dichloro-2,2-bis(p-chlorophenyl)ethylene. (7) Not reported since MRL > ½ the HRL. (8) Shows results > MRL, rather than > HRL, since MRL is greater than the HRL. In all cases the MRL is within the 10^{-4} to 10^{-6} risk range. (9) The MRLs used in UCM varied from below the ½ HRL to above the HRL. However, even the highest MRLs used are within the 10^{-4} to 10^{-6} risk range. (10) s-ethyl dipropylthiocarbamate..

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B. Contaminant Profiles

This section provides further details on the background, health, and occurrence information that the Agency used to evaluate each of the 11 candidate contaminants considered for regulatory determination. For each candidate, the Agency evaluated the available human and toxicological data, derived a health reference level, and evaluated the potential and/or likely occurrence and exposed population for the contaminant in public water systems. The Agency used the findings from these evaluations to determine whether the three SDWA statutory requirements were satisfied.

As discussed in section II.E, the Agency has also prepared a regulatory support document (USEPA, 2006a) that provides more details on the background, health, and occurrence information/analyses used to evaluate and make preliminary determinations for these 11 candidates.

1. Boron

a. *Background.* Boron, a metalloid, tends to occur in nature in the form of borates (e.g., boric acid, borax, boron oxide). Man-made releases are typically in the form of borates or boron halides (e.g., boron trichloride, boron trifluoride). Boron compounds are used in the production of glass, ceramics, soaps, fire retardants, pesticides, cosmetics, photographic materials, and high energy fuels (USGS, 2004; ATSDR, 1992).

Natural processes such as the weathering of rocks, volcanic activity, and geothermal steam contribute to the release of boron in the environment. Releases to the environment from human activities occur through the production, use, and disposal of boron-containing compounds (e.g., industrial emissions, fertilizer and herbicide runoff, hazardous waste deposits, and municipal sewage) (HSDB, 2004a; ATSDR, 1992).

Although quantitative data are not available on the man-made releases of most borates in the United States, two boron halide compounds, boron trichloride and boron trifluoride, are listed as Toxics Release Inventory (TRI) chemicals. TRI data for boron trichloride and boron trifluoride are reported for the years 1995 to 2003 (USEPA, 2006d). The TRI data show boron trichloride releases from facilities in 6 States and indicate that air emissions account for all of the total releases of boron trichloride (on- and off-site), which generally fluctuated in the range of hundreds of pounds per year during the period of record. The TRI data show boron trifluoride releases from facilities in 14 States and indicate that air emissions also account for nearly all of the boron trifluoride releases, which ranged in the tens of thousands of pounds annually.

b. *Health Effects.* The Institute of Medicine (IOM, 2001) of the National Academies categorizes boron as a possible trace mineral nutrient for humans. Boron is essential for plant growth and deficiency studies in animals and humans have provided some evidence that low intakes of boron affects cellular function and the activity of other nutrients. It may interact with Vitamin D and calcium homeostasis, influence estrogen metabolism, and play a role in cognitive function (IOM, 2001). Iyengar *et al.* (1988) reported an average dietary intake of 1.5 mg/day for male adults based on the Food and Drug Administration (FDA) Total Diet Study (TDS).

Some human oral data are available from cases where boron was ingested as a medical treatment. When the amount ingested was less than 3.68 mg/kg, subjects were asymptomatic, while doses of 20 and 25 mg/kg resulted in nausea and vomiting. Case reports and surveys of accidental poisonings indicate that the lethal doses of boron range from 15 to 20 grams (approximately 200 to 300 mg/kg) for adults, 5 to 6 grams (approximately 70 to 85 mg/kg) for children, and 2 to 3 grams (approximately 30 to 45 mg/kg) for infants (USEPA, 2004b).

The primary adverse effects seen in animals after chronic exposure to low doses of boron generally involve the testes and developing fetus. Chronic effects of dietary boron exposure in two-year studies included testicular atrophy and spermatogenic arrest in dogs, decreased food consumption,

suppressed growth, and testicular atrophy in rats, and decreased survival, testicular atrophy, and interstitial cell hyperplasia in mice. Although researchers observed some increases in tumor incidences in the liver and in subcutaneous tissues in mice, based on comparisons to historic controls, these tumors were determined not to be associated with exposure to boron from boric acid (USEPA, 2004b). Boron is not considered mutagenic and the Agency determined that there are inadequate data to assess the human carcinogenic potential for boron (USEPA, 2004c).

In developmental studies with rats, mice, and rabbits, oral exposure to boric acid resulted in decreased pregnancy rate, increased prenatal mortality, decreased fetal weights, and increased malformations in fetuses and pups. However, these reproductive effects were associated with maternal toxicity including changes in maternal organ weights, body weights, weight gain, and increased renal tubular dilation and/or regeneration (Price *et al.*, 1990, 1994, 1996; Heindel *et al.*, 1992, 1994; Field *et al.*, 1989). Reproductive effects in males were noted in the subchronic and chronic studies described in the preceding paragraphs.

The EPA RfD for boron is 0.2 mg/kg/day (USEPA, 2004c) based on developmental effects in rats from two studies (Price *et al.*, 1996; Heindel *et al.*, 1992). The RfD was derived using the benchmark dose (BMD) method (bench mark dose level or BMDL from Allen *et al.*, 1996). EPA calculated the HRL of 1.4 mg/L or 1,400 [mu]g/L for boron using the RfD of 0.2 mg/kg-day and a 20 percent screening relative source contribution.

EPA also evaluated whether health information is available regarding the potential effects on children and other sensitive populations. Studies in rats, mice, and rabbits identify the developing fetus as potentially sensitive to boron. Price *et al.* (1996) identified a LOAEL of 13.3 mg/kg-day and an NOAEL of 9.6 mg/kg-day in the developing fetus, based on decreased fetal body weight in rats. Accordingly, boron at concentrations greater than the HRL might have an effect on prenatal development. Individuals with severely impaired kidney function might also be sensitive to boron exposure since the kidney is the most important route for excretion.

c. *Occurrence Analyses.* The National Inorganics and Radionuclides Survey (NIRS) included boron as an analyte. Using data from NIRS, EPA performed an initial evaluation of occurrence and exposure at levels greater than 700 [mu]g/L (½ the HRL) and greater than 1,400 [mu]g/L (the HRL for boron). The NIRS data indicate that approximately 4.3 percent (or 43) of the 989 ground water PWSs sampled had detections of boron at levels greater than 700 [mu]g/L, affecting approximately 2.9 percent of the population served (or 42,700 people from 1.48 million). Approximately 1.7 percent (or 17) of 989 ground water PWSs sampled had detections of boron at levels greater than 1,400 [mu]g/L, affecting approximately 0.4 percent of the population served (6,400 people from 1.48 million) (USEPA, 2006a and 2006c).

Because NIRS did not contain data for surface water systems, the Agency evaluated the results of a survey funded by the American Water Works Association Research Foundation (Frey *et al.*, 2004) to gain a better understanding of the potential occurrence of boron in surface water systems. The AWWARF study recruited 189 PWSs representing 407 source waters that covered 41 states. Of these 407 PWS source water samples, 342 were returned and 341 were analyzed for boron. Of these 341 samples, approximately 67 percent (or 228) represented ground water sources and 33 percent (or 113) represented surface water sources. None of the 113 surface water sources exceeded the boron HRL of 1,400 [mu]g/L and the maximum concentration observed in surface water was 345 [mu]g/L. Extrapolation of the data indicates that 95 percent of the ground water detections had boron levels less than 1,054 [mu]g/L; the maximum observed concentration in ground water was approximately 3,300 [mu]g/L. Seven of the 228 ground water sources (from 5 systems) had boron concentrations greater than 1,400 [mu]g/L (Seidel, 2006).

d. *Preliminary Determination.* The Agency has made a preliminary determination not to regulate boron with an NPDWR. While boron was found at levels greater than the HRL (and ½ the HRL) in several of the ground water systems surveyed by NIRS, it was not found at levels greater than the HRL (or ½ the HRL) in the surface waters sources evaluated in the AWWARF study. Taking this surface water information into account, the Agency believes that the overall national occurrence and exposure from both surface and ground water systems together is likely to be lower than the values observed for the NIRS ground water data. Because boron is not likely to occur at levels of concern when considering both surface and ground waters systems, the Agency believes that a national primary drinking water regulation does not present a meaningful opportunity for health risk reduction.

The Agency encourages those States with public water systems that have boron at concentrations above the HRL to evaluate site-specific protective measures and to consider whether State-level guidance (or some other type of action) is appropriate. The Agency also plans to update the Health Advisory for boron to provide more recent health information. The updated Health Advisory will provide information to any States with public water systems that may have boron above the HRL.

2 and 3. Mono- and Di-Acid Degradates of Dimethyl Tetrachloroterephthalate (DCPA)

a. *Background.* Dimethyl tetrachloroterephthalate (DCPA), a synthetic organic compound (SOC) marketed under the trade name ''Dacthal,'' is a pre-emergent herbicide historically used to control weeds in ornamental turf and plants, strawberries, seeded and transplanted vegetables, cotton, and field beans. As of 1990, more than 80 percent of its use was for turf, including golf courses and home lawns (USEPA, 1990b). On July 27, 2005, in response to concerns about groundwater contamination (especially for one of the DCPA degradates), the Agency published a **Federal Register** notice announcing that the registrant for Dacthal had voluntarily terminated a number of uses for products containing DCPA (70 FR 43408; USEPA, 2005f). The only uses retained were those for use on sweet potatoes, eggplant, kale and turnips.

DCPA is not especially mobile or persistent in the environment. Biodegradation and volatilization are the primary dissipation routes. Degradation of DCPA forms two breakdown products, the mono-acid degradate (or monomethyl tetrachloroterephthalate or MTP) and the di-acid degradate (tetrachloroterephthalic acid or TPA). The di-acid, which is the major degradate, is unusually mobile and persistent in the field, with a potential to leach into water (USEPA, 1998c).

Several studies and reports provide estimates of the amount of DCPA used during the 1990s in the United States. The Agency estimated that 1.6 million pounds of DCPA active ingredient a.i. were used annually in the early 1990s (USEPA, 1998c). USGS estimated that approximately 998 thousand pounds of DCPA a.i. were used annually circa 1992 (Thelin and Gianessi, 2000). The National Center for Food and Agricultural Policy (NCFAP, 2004) estimates that approximately 1.7 million

pounds of DCPA a.i. were used in 1992 and approximately 600 thousand pounds a.i. were used in 1997 (NCFAP, 2004). The NCFAP data suggest a decrease in the use of DCPA from the early to the late 1990s.

b. *Health Effects.* Currently, no subchronic or chronic studies are available to assess the toxicological effects of MTP (the mono-acid degradate) and 3 studies in rats (30 and 90-day feeding studies and a one-generation reproductive study) are available for TPA (the di-acid degradate). The effects of exposure were mild (weight loss and diarrhea) and occurred at doses greater than or equal to 2,000 mg/kg/day. No reproductive effects were observed.

The present toxicity database for MTP and TPA is not sufficient to derive RfDs for these two chemicals. However, since the available data indicate that neither MTP nor TPA are more toxic than their parent compound, DCPA, the Agency suggests that the RfD for the DCPA parent would be protective against exposure from these two DCPA metabolites (USEPA, 1998c). Both compounds are formed in the body from the DCPA parent and therefore, the toxicity of these degradates is reflected in the toxicity of the parent. The RfD for DCPA is 0.01 mg/kg/day based on a chronic rat study (ISK Biotech Corporation, 1993) with a NOAEL of 1.0 mg/kg/day and an uncertainty factor of 100 for rat to human extrapolation and intra-species variability.

No carcinogenicity studies have been performed using either TPA or MTP. Based on the cancer data for the parent and lack of mutagenicity for TPA and DCPA, the Agency (USEPA, 2004d) concludes that TPA is unlikely to pose a cancer risk. Klopman *et al.* (1996) evaluated the carcinogenic potential of TPA based on its chemical and biological properties, as well as by a variety of computational tools, and determined that it did not present any substantial carcinogenic risk. There was suggestive evidence that DCPA could be carcinogenic based on an increased incidence of thyroid and liver tumors in rats. The presence of hexachlorobenzene and dioxin as impurities in the material tested could have contributed to the cancer risk.

Using the DCPA RfD of 0.01 mg/kg/day (USEPA, 1994) and a 20 percent screening relative source contribution, the Agency calculated an HRL of 0.07 mg/L or 70 [mu]g/L for DCPA and used this HRL for TPA and MTP.

EPA also evaluated whether health information is available regarding the potential effects on children and other sensitive populations. There are no data that identify a particular sensitive population for DCPA exposure. Results of a single developmental study indicate that exposure to pregnant dams with doses less than or equal to 2,500 mg/kg/day of TPA via gavage did not have an adverse effect on the fetus. EPA did not identify any data that suggest gender-related differences in toxicity or sensitivity in the elderly.

c. *Occurrence.* EPA included the DCPA mono- and di-acid degradates (MTP and TPA) as analytes in the UCMR 1. The analysis results reported for UCMR 1 are the sum of both the mono- and di-acid degradates. EPA converted the analysis result for the degradates to the parent DCPA equivalent and performed an initial evaluation of occurrence and exposure at levels greater than 35 [mu]g/L (½ the HRL) and greater than 70 [mu]g/L (the HRL). As previously discussed, EPA used the HRL derived for the DCPA parent because it includes the toxicity for the mono- and di-acid degradates. While the UCMR 1 data indicate that the DCPA degradates were the most commonly reported analytes in the monitoring survey (detected at an MRL of 1 [mu]g/L in 772 samples from 175 of the 3,868 PWSs sampled), very few systems exceeded the health level of concern. PWSs with detections were found in 24 States and 1 Territory. The UCMR 1 data indicate that approximately 0.05 percent (or 2) of the 3,868 PWSs sampled had a detection of the DCPA degradates at levels greater than 35 [mu]g/L, affecting approximately 0.33 percent of the population served (or 739,000 people from 225 million). Approximately 0.03 percent (or 1) of the 3,868 PWSs sampled have a detection of the DCPA degradates at levels greater than 70 [mu]g/L, affecting less than 0.01 percent of the population served (or 500 people from 225 million) (USEPA, 2006a and 2006b).

EPA also evaluated several sources of supplemental occurrence information for the DCPA parent, the mono-acid degradate and/or the di-acid degradate. These supplemental sources include:

<bullet≤ The National Pesticide Survey (NPS),

<bullet≤ The provisional pesticide results from the 1992–2001 USGS NAWQA survey of ambient surface and ground waters across the U.S., and

<bullet≤ Studies performed by the DCPA or dacthal registrant.

As part of the National Pesticide Survey, EPA collected samples from approximately 1,300 community water systems and rural drinking water wells between 1988 and 1990. The NPS included monitoring for the DCPA parent and the di-acid degradate. The DCPA parent was not detected in any wells (using a detection limit of 0.06 [mu]g/L). While the di-acid degradate was detected in 49 of 1,347 wells (using a detection limit of 0.1 [mu]g/L), the maximum reported concentration of 7.2 [mu]g/L did not exceed the HRL of 70 [mu]g/L (USEPA, 1990a).

The USGS NAWQA program included the DCPA parent and the mono-acid degradate as analytes in its 1992–2001 monitoring survey of ambient surface and ground waters across the United States. EPA evaluated the results of the provisional data, which are available on the Web (Martin *et al.*, 2003; Kolpin and Martin, 2003). While the USGS detected the DCPA parent in both surface and ground waters, at least 95 percent of the samples from the various land use settings were less than or equal to 0.007 [mu]g/L. The estimated maximum surface water concentration, 40 [mu]g/L (agricultural setting), and the estimated maximum ground water concentration, 10 [mu]g/L (agricultural setting), are both less than 70 [mu]g/L (the DCPA HRL). While the USGS detected the mono-acid degradate in both surface waters and ground waters, at least 95 percent of the samples from the various land use settings were less than 0.07 [mu]g/L (the reporting limit for the mono-acid degradate). The maximum surface water concentration, 0.43 [mu]g/L (agricultural setting), and the maximum ground water concentration, 1.1 [mu]g/L (agricultural setting), are both less than 70 [mu]g/L (the DCPA HRL, which includes the toxicity of the degradates).

Beginning in 1992, the registrant for DCPA performed two small-scale ground water occurrence studies in New York and California over a period of 17 and 22 months, respectively. The registrant monitored for the DCPA parent and both of its degradates. The average reported values, which are the sum of the parent and its degradates, were 50.36 [mu]g/L in New York and 12.75 [mu]g/L in California. Neither average value exceeded the HRL of 70 [mu]g/L (USEPA, 1998c).

d. *Preliminary Determination.* The Agency has made a preliminary determination not to regulate the DCPA mono-acid degradate and/or the DCPA di-acid degradate with an NPDWR. Because these degradates appear to occur infrequently at health levels of concern in PWSs, the Agency believes that a national primary drinking water regulation does not present a meaningful opportunity for health risk reduction. While the Agency recognizes that these degradates have been detected in the PWSs monitored under the UCMR 1, only 1 PWS had a detect above the HRL.

The Agency encourages those States with public water systems that have detects for these degradates to evaluate site-specific protective measures and to consider whether State-level guidance (or some other type of action) is appropriate. The Agency also plans to update the Health Advisory for the DCPA parent to include the mono and di acid degradates, as well as any recent health information related to these compounds. The updated Health Advisory will provide information to any States with public water systems that may have DCPA degradates at levels above the HRL.

4. 1,1-Dichloro-2,2-bis(*p*-chlorophenyl) ethylene (DDE)

a. *Background.* DDE is a primary metabolite of DDT,[15] a pesticide once used to protect crops and eliminate disease-carrying insects in the U.S. until it was banned in 1973. DDE itself has no commercial use and is only found in the environment as a result of contamination and/or breakdown of DDT. While DDE tends to adsorb strongly to surface soil and is fairly insoluble in water, it may enter surface waters from runoff that contains soil particles contaminated with DDE. In both soil and water, DDE is subject to photodegradation, biodegradation, and volatilization (ATSDR, 2002).

b. *Health Effects.* DDE is not produced as a commercial product. This has limited the numbers of conventional studies that have been performed to assess toxicological properties. Limited data on DDE, mostly from a National Cancer Institute (NCI) bioassay, suggest that the liver is the primary target organ in mammalian species. However, the NCI study did not evaluate a full array of noncancer endpoints. There is an RfD of 0.0005 mg/kg/day for the parent pesticide DDT based on a NOAEL of 0.05 mg/kg/day from a dietary subchronic study (USEPA, 1996b). In this study, liver lesions were identified at a LOAEL of 0.25 mg/kg/day. Data on DDT identify effects on the nervous and hormonal systems as adverse effects that might also be seen with DDE because it is one of DDT's primary metabolites. The limited data for DDE suggest that any effects on the nervous system are less severe than those seen with DDT. Endocrine effects from DDE are discussed in this section.

Based on animal studies DDE is likely to be carcinogenic to humans. This classification is based on increases in the incidence of liver tumors, including carcinomas, in two strains of mice and in hamsters after dietary exposure to DDE. Some epidemiological studies suggest a possible association of the levels of DDE in serum with breast cancer. However, other studies with similar methodologies do not show any association. DDE was mutagenic in mouse lymphoma L5178Y and Chinese hamster V79 cells but negative in the Ames assay. In the 1988 IRIS, EPA calculated an oral slope factor of 0.34 $(mg/kg/day)^{-1}$ for DDE (USEPA, 1988a). For this regulatory determination, EPA calculated an oral slope factor from the same data set (from the 1988 IRIS) using the EPA 1999 Cancer Guidelines (USEPA, 1999a). The revised slope factor is 1.67×10^{-1} $(mg/kg/day)^{-1}$ resulting in a one-in-a-million cancer-risk (HRL) of 0.2 [mu]g/L.

There are some indications that DDE has an adverse impact on the immune system (Banerjee *et al.*, 1996). Oral exposures to 22 mg/kg/day for 6 weeks suppressed serum immunoglobin levels and antibody titers. Inhibition of leucocytes and macrophage migration were observed at the cellular level. Considerable evidence exists that DDE can act as an endocrine disruptor since it binds to the estrogen and androgen receptors. DDE has a stronger affinity for the androgen receptor than for the estrogen receptor. It competes with testicular hormones for the androgen receptor leading to receptor-related changes in gene expression (Kelce *et al.*, 1995).

EPA evaluated whether health information is available regarding the potential effects on children and other sensitive populations. Children and adolescents may be sensitive populations for exposure to DDE due to its endocrine disruption properties. Some data suggest that DDE can delay puberty in males (ATSDR, 2002).

c. *Occurrence.* EPA included DDE as an analyte in the UCMR 1. Because the HRL for DDE (0.2 [mu]g/L) is lower than the minimum reporting limit (MRL) used for monitoring (0.8 [mu]g/L), EPA used the MRL value to evaluate occurrence and exposure. The MRL is within the 10^{-4} to the 10^{-6} cancer risk range for DDE. In evaluating the UCMR 1 data, EPA found that approximately 0.03 percent (or 1) of the 3,867 PWSs sampled had a detection of DDE at the MRL of 0.8 [mu]g/L, affecting approximately 0.01 percent of the population served (or 18,000 people from 226 million) (USEPA, 2006a and 2006b).

The USGS NAWQA program included DDE as an analyte in its 1992–2001 monitoring survey of ambient surface and ground waters across the United States. EPA evaluated the results of the provisional data, which are available on the Web (Martin *et al.*, 2003; Kolpin and Martin, 2003), as a supplemental source of occurrence information. While the USGS detected DDE in both surface and ground waters, 95 percent of the samples from the various land use settings were less than 0.006 [mu]g/L (the USGS reporting limit). The maximum surface water concentration, 0.062 [mu]g/L (agricultural setting), and the maximum ground water concentration, 0.008 [mu]g/L (agricultural setting), are both less than 0.2 [mu]g/L (the DDE HRL).

d. *Preliminary Determination.* The Agency has made a preliminary determination not to regulate DDE with an NPDWR. Because DDE appears to occur infrequently at levels of concern in PWSs, the Agency believes that a national primary drinking water regulation does not present a meaningful opportunity for health risk reduction. DDE was detected in only one of the PWSs monitored under the UCMR 1 at a level greater than the MRL (0.8 [mu]g/L), a concentration that is within the 10^{-4} to the 10^{-6} cancer risk range. In addition, ambient water data from the USGS indicate that the maximum concentrations detected in surface and ground water were less than the HRL of 0.2 [mu]g/L.

EPA recognizes that DDE is listed as a probable human carcinogen. For this reason, the Agency encourages those States with public water systems that might have DDE above the HRL to evaluate site-specific protective measures and to consider whether State-level guidance (or some other type of action) is appropriate.

5. 1,3-Dichloropropene (1,3-DCP; Telone)

a. *Background.* 1,3-Dichloropropene (1,3-DCP), a synthetic volatile organic compound, is used as a pre-plant soil fumigant to control nematodes and other pests in soils to be planted with all types of food and feed crops. 1,3-DCP is typically injected 12'' to 18'' beneath the soil surface and can only be used by certified handlers (USEPA, 1998b). To mitigate risks to drinking water, 1999 labeling requirements restrict the use of 1,3-DCP:

<bullet≤ In areas with shallow ground water and vulnerable soils in certain northern tier States (ND, SD, WI, MN, NY, ME, NH, VT, MA, UT, and MT);

<bullet≤ In fields within 100 feet of a drinking water well; and

<bullet≤ In areas overlying karst [16] geology.

[15] 1,1,1-trichloro-2,2-bis(p-chlorophenyl)ethane.

[16] Karst is a type of typography that is formed by the dissolution and collapse of soluble rocks (typically limestone and dolomite). According to the Karst Waters Institute, as excerpted by USGS (2006), common geological characteristics of karst regions that influence human use of its land and water resources include ground subsidence,

Estimates of national annual use during the 1990s vary widely, from approximately 23 to 40 million pounds of active ingredient a.i. Based on information from a 1991 data call-in and other sources, EPA estimates that approximately 23 million pounds of 1,3-DCP a.i. were used annually from 1990 to 1995 (USEPA, 1998b). NCFAP (2004) estimates that approximately 40 million pounds a.i. were used in 1992 and approximately 35 million pounds a.i. were used in 1997.

1,3-Dichloropropene is listed as a TRI chemical and releases are reported from facilities in 17 States over a time period covering 1988 to 2003 (although not all States had facilities reporting releases every year) (USEPA, 2006e). Air emissions appear to account for most of the on-site (and total) releases and generally declined between 1988 and 2003. A sharp decrease in air emissions is evident between 1995 and 1996. Surface water discharges are minor compared to air emissions and no obvious trend is evident between 1988 and 2003. Reported underground injection, releases to land, and off-site releases are generally insignificant.

b. *Health Effects.* Chronic and subchronic exposures to 1,3-DCP at doses of 12.5 mg/kg/day and above in animal dietary studies indicate that 1,3-DCP is toxic to organs involved in metabolism (liver), excretion of conjugated metabolites (e.g., urinary bladder and the kidney) and organs along the portals of entry (e.g., forestomach for oral administration; mucous membrane of the nasal passage and lungs for inhalation exposure). Exposure to 1,3-DCP has not been shown to cause reproductive or developmental effects. Neither reproductive nor developmental toxicity were observed in a two-generation reproductive study in rats or in developmental studies in rats and rabbits at maternal inhalation concentrations up to 376 mg/m^3 (USEPA, 2000a). Even concentrations that produced parental toxicity did not produce reproductive or developmental effects (USEPA, 2000a).

An RfD of 0.03 mg/kg/day for 1,3-DCP (USEPA, 2000a) has been established using a benchmark dose (BMD) analysis based on a two-year chronic bioassay (Stott *et al.*, 1995) in which chronic irritation (forestomach hyperplasia) and significant body weight reduction were the critical and co-critical effects, respectively. A reference concentration (RfC) of 0.02 mg/m^3 was derived from a two-year bioassay (Lomax *et al.*, 1989), which observed histopathology in the nasal epithelium.

Under the proposed cancer risk assessment guidelines, the weight of evidence for evaluation of 1,3-DCP's ability to cause cancer suggest that it is likely to be carcinogenic to humans (USEPA, 2000a). This characterization is supported by tumor observations in chronic animal bioassays for both inhalation and oral routes of exposure.

The oral cancer slope factors calculated from chronic dietary, gavage and inhalation data ranged from 5×10^{-2} to 1×10^{-1} $(mg/kg/day)^{-1}$. Due to uncertainties in the delivered doses in some studies, EPA (IRIS) recommended using the oral slope factor of 1×10^{-1} $(mg/kg/day)^{-1}$ from an NTP (1985) study. Using this oral slope factor, EPA calculated an HRL of 0.4 [mu]g/L at the 10^{-6} cancer risk level.

EPA also evaluated whether health information is available regarding the potential effects on children and other sensitive populations. No human or animal studies are available that have examined the effect of 1,3-DCP exposure on juvenile subjects. Therefore, its effects on children are unknown. Developmental studies in rats and rabbits show no evidence of developmental effects and therefore it is unlikely that 1,3-DCP causes developmental toxicity.

c. *Occurrence.* EPA included 1,3-DCP as an analyte in the UCM Round 1 and UCM Round 2 surveys. The MRLs for UCM Round 1 ranged from 0.02 to 10 [mu]g/L and the MRLs for UCM Round 2 ranged from 0.08 to 1 [mu]g/L. EPA also analyzed for 1,3-DCP using the samples from the small systems that were included in the UCMR 1 survey. The MRL used for the UCMR 1 survey was 0.5 [mu]g/L. Because some of these reporting limits exceeded the thresholds of interest, the occurrence analyses may result in an underestimate of systems affected (USEPA, 2006a, 2006b and 2006c). However, the MRL values used for UCM Round 1 and UCM Round 2 as well as UCMR 1 are within the 10^{-4} to the 10^{-6} cancer risk range.

The UCM Round 1 Cross Section data indicate that approximately 0.16 percent (or 15) of the 9,164 PWSs sampled had detections of 1,3-DCP at levels greater than 0.2 [mu]g/L (½ the HRL), affecting approximately 0.86 percent of the population served (or 438,000 of 51 million). The UCM Round 1 Cross Section data also indicate the same values when the data are analyzed using 0.4 [mu]g/L (the HRL). That is, 0.16 percent (or 15) of 9,164 PWSs sampled had detections greater than 0.4 [mu]g/L (the HRL), affecting approximately 0.86 percent of the population served (or 438,000 of 51 million people). The 99th percentile of all detections is 2 [mu]g/L and the maximum reported value is 2 [mu]g/L.

The UCM Round 2 Cross Section data indicate that approximately 0.30 percent (or 50) of the 16,787 PWSs sampled had detections of 1,3-DCP at levels greater than 0.2 [mu]g/L (½ the HRL), affecting approximately 0.42 percent of the population served (or 193,000 of 46 million). The UCM Round 2 Cross Section data indicate that approximately 0.23 percent (or 38) of the 16,787 PWSs sampled had detections of 1,3-DCP at levels greater than 0.4 [mu]g/L (the HRL), affecting approximately 0.33 percent of the population served (or 152,000 of 46 million). The 99th percentile of all detections is 39 [mu]g/L and the maximum reported value is 39 [mu]g/L.

Because the sample preservative used may have resulted in potential underestimates of occurrence for the UCM Rounds 1 and 2 data, EPA subsequently analyzed for 1,3-DCP using the samples provided by 796 of the small systems included in the recent UCMR 1 survey. None of the 3,719 samples from these 796 small systems (serving a population of 2.8 million) had detects of 1,3-DCP at levels greater than 0.5 [mu]g/L (the minimum reporting limit used for the analysis of 1,3-DCP and a level that is slightly higher than the HRL).

EPA also evaluated several sources of supplemental information, which included:

<bullet≤ The National Pesticide Survey,

<bullet≤ The Pesticides in Ground Water Database,

<bullet≤ A well water survey submitted by the registrant of Telone (1,3-DCP),

<bullet≤ The USGS VOC National Synthesis Random Source Water Survey, and

<bullet≤ The USGS VOC National Synthesis Focused Source Water Survey.

As part of the National Pesticide Survey, EPA collected samples from approximately 1,300 community water systems and rural drinking water wells between 1988 and 1990. The NPS included *cis* and *trans* 1,3-DCP as analytes in the monitoring survey. Neither compound was detected in the survey using a minimum reporting limit of 0.010 [mu]g/L (USEPA, 1990a).

The Pesticides in Ground Water Database (USEPA, 1992b) indicates that 1,3-DCP was found in 6 of 21,270 ground water wells sampled in 7 States. The 6 wells with positive detections for 1,3-DCP included 3 wells in California (at concentrations ranging from 0.890 to 31.0 [mu]g/L), 2 wells in Florida (at concentrations of 0.279 to 7.83 [mu]g/L), and 1 well in Montana (at concentrations of 18 to 140 [mu]g/L). While most or all of these 6 wells had

sinkhole collapse, ground water contamination, and unpredictable water supply.

concentrations greater than the HRL for 1,3-DCP, the overall percentage of positive wells detections was less than 0.1 percent.

In 1998, the registrant for Telone (1,3-DCP) submitted a private well water study to the Agency. The well water survey covered 5 regions where Telone was used intensively and evaluated 518 wells (5,800 samples) for the presence of 1,3-DCP. Of the 518 wells, 65 had detectable levels of 1,3-DCP and/or its metabolites at levels greater than 0.015 [mu]g/L (the detection limit for 1,3-DCP was 0.015 [mu]g/L and the metabolites were 0.023 [mu]g/L). None of the wells exceeded 0.2 [mu]g/L (a level half the EPA-derived HRL for 1,3-DCP) (USEPA, 2004e and 2004f).

For the Random Source Water Survey, the USGS collected samples from 954 source waters that supply community water systems between 1999 and 2000. For the Focused Source Water Survey, the USGS collected 451 samples from 134 source waters that supply community water systems between 1999 and 2001. The USGS included 1,3-DCP as an analyte in both surveys. The USGS did not detect 1,3-DCP in any of the source water samples from the Random Source Water Survey using a reporting limit of 0.2 [mu]g/L (a level that is one-half the HRL for 1,3-DCP). In addition, the USGS did not detect 1,3-DCP in any of the source water samples in the Focused Source Water Survey using a detection limit of 0.024 [mu]g/L for cis-1,3-dichloropropene and 0.026 [mu]g/L for trans-1,3-dichloropropene (levels that are about 16 times lower than the HRL for 1,3-DCP) (Ivahnenko *et al.*, 2001; Grady, 2003; Delzer and Ivahnenko, 2003a).

d. *Preliminary Determination.* The Agency has made a preliminary determination not to regulate 1,3-DCP with an NPDWR. Because 1,3-DCP appears to occur infrequently at health levels of concern in PWSs, the Agency believes that a national primary drinking water regulation does not present a meaningful opportunity for health risk reduction. While 1,3-DCP was detected in the UCM Round 1 (late 1980s) and the UCM Round 2 (mid 1990s) surveys, it was not detected in a subsequent evaluation of 796 small systems from the UCMR 1 survey. In addition, the USGS did not detect 1,3-DCP in two occurrence studies performed between 1999 and 2001 using monitoring levels that were lower than the HRL. EPA believes the 1999 pesticide labeling requirements, which are intended to mitigate risks to drinking water, may be one reason for the lack of occurrence of 1,3-DCP at levels of concern in subsequent monitoring surveys.

EPA recognizes that 1,3-dichloropropene is listed as a probable human carcinogen. For this reason, the Agency encourages those States with public water systems that may have 1,3-dichloropropene above the HRL to evaluate site-specific protective measures and to consider whether State-level (or some other type of action) is appropriate. The Agency also plans to update the Health Advisory document for 1,3-DCP to provide more recent health information. The updated Health Advisory will provide information to any States with public water systems that may have 1,3-DCP above the HRL.

6 and 7. 2,4- and 2,6-Dinitrotoluenes (2,4- and 2,6-DNT)

a. *Background.* 2,4- and 2,6-dinitrotoluene (DNT), semi-volatile organic compounds, are two of 6 isomers of dinitrotoluene. Dinitrotoluenes are used in the production of polyurethane foams, automobile air bags, dyes, ammunition, and explosives, including trinitrotoluene or TNT (HSDB, 2004b and 2004c; ATSDR, 1998). Neither 2,4- nor 2,6-DNT occur naturally. They are generally produced as individual isomers or as a mixture called technical grade DNT (tg-DNT). Technical grade DNT primarily contains a mixture of 2,4-DNT and 2,6-DNT with the remainder consisting of the other isomers and minor contaminants such as TNT and mononitrotoluenes (HSDB, 2004b).

No recent quantitative estimates of DNT production or use are available. The Hazardous Substances Data Bank (HSDB, 2004b) cites a 1980 EPA Ambient Water Quality Criteria Document that places combined 2,4- and 2,6-DNT production at 272,610,000 pounds in 1975.

Both 2,4-DNT and 2,6-DNT are listed as TRI chemicals. TRI data for 2,4-DNT are reported from facilities in 21 States over a time period covering 1988 to 2003. Total releases nationally in 2003 were 14,899 lbs. Releases of all kinds (off-site releases and on-site air, surface, underground injection, and land releases) declined in the early 1990s, and then peaked again around 1999–2001. On-site air emissions and surface water releases of 2,4-DNT were generally the most consistent (least fluctuating) types of releases, with surface water releases generally declining over the period on record (USEPA, 2006f).

TRI data for 2,6-DNT are reported from facilities in 10 States over a time period covering 1988 to 2003 (with no more than 9 States having reporting facilities in any one year). Total reported releases for 2003 were 10,937 lbs. Trends for 2,6-DNT are similar to those for 2,4-DNT. The TRI data for 2,6-DNT show a trend of declining releases in the late 1980s and early 1990s, and a subsequent peak around 1999–2001. On-site air emissions and surface water discharges are the most consistent types of release for 2,6-DNT and surface water discharges exhibit a declining trend (USEPA, 2006f).

In addition, TRI lists mixed DNT isomer releases as a separate category over the same time period (1990–2003). TRI releases of mixed isomers were reported from facilities in 9 States, with no more than 7 States having reporting facilities in any one year. Total releases in 2003 were 13,790 lbs. Underground injections made up the bulk of on-site releases during the 1990s, but diminished thereafter. Air emissions remained relatively constant. Surface water discharges and releases to land were generally insignificant but peaked in 2003. Off-site releases varied widely. Total releases peaked in 1993 and 1997, and generally diminished in recent years (USEPA, 2006f).

b. *Health Effects.* In experimental animal studies, 2,4- and 2,6-DNT appear to be acutely toxic at moderate to high levels (LD_{50}'s [17] ranging from 180 to 1,954 mg/kg) when administered orally. In subacute studies (4 weeks) conducted by Lee *et al.* (1978), dogs, rats, and mice were fed 2,4-DNT and studied for toxic effects. A NOAEL of 5 mg/kg/day was established; decreased body weight gain and food consumption, neurotoxic signs, and lesions in the brain, kidneys, and testes occurred at 25 mg/kg/day (the highest dose tested).

Subchronic studies in mice, rats, and dogs that administered 2,4- and 2,6-DNT in the diet produced similar effects in all species. All species exposed to 2,4-DNT exhibited methemoglobinemia, anemia, bile duct hyperplasia sometimes accompanied by hepatic degeneration, and depressed spermatogenesis. Neurotoxicity and renal degeneration occurred in dogs at a dose level of 20 mg/kg/day of 2,6-DNT (Lee *et al.*, 1976). At a dose level of 25 mg/kg/day of 2,4-DNT, male and female dogs developed impaired muscle movement and paralysis, methemoglobinemia, aspermatogenesis, hemosiderosis of the spleen and liver, cloudy swelling of the kidneys, and lesions of the brain (Ellis *et al.*, 1985).

[17] LD_{50} = An estimate of a single dose that is expected to cause the death of 50% of the exposed animals. It is derived from experimental data.

These doses were determined to be LOAELs for these studies.

2,4-DNT has been shown to cause reproductive effects in rats, mice, and dogs (Ellis *et al.*, 1979; Lee *et al.*, 1985; Hong *et al.*, 1985; Ellis *et al.*, 1985). Ellis *et al.* (1979) observed effects in rats following dietary exposure after a dose of 35 mg/kg/day but not 5 mg/kg/day over 3 generations. Male mice fed 2,4-DNT for 13 weeks exhibited testicular degeneration and atrophy and decreased spermatogenesis at 95 mg/kg/day (Hong *et al.*, 1985). In another reproductive study, dogs exhibited mild to severe testicular degeneration and reduced spermatogenesis (Ellis *et al.*, 1985) when administered 2,4-DNT in capsules at 25 mg/kg/day. There are currently no studies of the reproductive or developmental toxicity of 2,6-DNT although a subchronic study in dogs identified atrophy of spermatogenic cells in males suggesting a one- or two-generation study as a data need for 2,6-DNT.

Some studies evaluated the effects of DNT in the form of a technical mixture (tg-DNT). In a study by Price *et al.* (1985), the teratogenic potential of tg-DNT (containing approximately 76 percent 2,4-DNT and 19 percent 2,6-DNT) was investigated in rats. The study was conducted in two phases to evaluate the possible teratogenicity of DNT as well as DNT effects on postnatal development. For the first phase, rats were administered 0, 14, 35, 37.5, 75, 100, or 150 mg/kg/day of DNT in corn oil by gavage. In the postnatal phase, rats were administered 14, 35, 37.5, 75, or 100 mg/kg/day of DNT in corn oil by gavage. The NOAEL and LOAEL for developmental toxicity were 14 and 35 mg/kg/day, respectively, based on significant increases in relative liver and spleen weight in the fetuses of dams administered DNT at levels of 35 mg/kg/day or greater. No teratogenic toxicity was seen in the study rats.

In chronic exposures, oral dietary administration of 2,4-DNT to dogs primarily affected the nervous system, erythrocytes, and biliary tract (Ellis *et al.*, 1979, 1985). Based on neurotoxicity, hematologic changes, and effects on the bile ducts in dogs, the LOAEL was determined to be 1.5 mg/kg/day and the NOAEL was 0.2 mg/kg/day. EPA established an RfD of 0.002 mg/kg/day for 2,4-DNT (USEPA, 1992c) based on this study. An uncertainty factor of 100, to account for interspecies and intraspecies variability, was applied to derive the RfD.

EPA established an RfD of 0.001 mg/kg/day for 2,6-DNT (USEPA, 1992c). This RfD was also based on neurotoxicity, Heinz body formation, biliary tract hyperplasia, liver and kidney histopathology, and death in beagle dogs that were fed gelatin capsules containing 2,6-DNT daily for up to 13 weeks (Lee *et al.*, 1976). The NOAEL for this study was 4 mg/kg/day, and an uncertainty factor of 3,000 (100 for inter- and intra-species variability, 10 for the use of a subchronic study, 3 to account for the limited database) was applied to derive the RfD.

DNT is likely to be carcinogenic to humans (classified as a B2 carcinogen; USEPA, 1990c). This is based on significant increases in hepatocellular carcinoma and mammary gland tumors in female rats fed DNT (98 percent 2,4-DNT with 2 percent 2,6-DNT) in the diet in a two-year study (Ellis *et al.*, 1979). The tumor incidence in the female rats was used to establish a slope factor of 6.67×10^{-1} according to the 1999 EPA guidelines. Concentrations of 5 [mu]g/L, 0.5 [mu]g/L, and 0.05 [mu]g/L are associated with carcinogenic risks of 10^{-4}, 10^{-5}, and 10^{-6} respectively. There were no studies found in the literature that evaluated the effects of 2,4- or 2,6-DNT on children. There is evidence that the pups and fetuses from dams administered tg-DNT had significant increases in relative liver and spleen weights (Price *et al.*, 1985). DNT toxicity may be different in children, compared to adults, since it undergoes bioactivation in the liver and by the intestinal microflora (ATSDR, 1998). Newborns may be more sensitive to DNT-related methemoglobinemia because an enzyme that protects against increased levels of methemoglobin is inactive for a short duration immediately after birth (Gruener 1976; ATSDR, 1998). However, there are no experimental data on differences in children's responses to 2,4-/2,6-DNT.

c. *Occurrence.* EPA included both 2,4- and 2,6-DNT as analytes in the UCMR 1. Because the HRL for both 2,4- and 2,6-DNT (0.05 [mu]g/L) is lower than the minimum reporting limit used for monitoring (MRL of 2 [mu]g/L), EPA used the MRL to evaluate occurrence and exposure. The MRL is within the 10^{-4} to the 10^{-6} cancer risk range for either 2,4- or 2,6-DNT. In evaluating the UCMR 1 data, EPA found that 1 of the 3,866 PWSs sampled (or 0.03 percent) detected 2,4-DNT at the MRL of 2 [mu]g/L, affecting 0.02 percent of the population served (or 38,000 people from 226 million). None of the 3,866 PWSs sampled (serving 226 million) detected 2,6-DNT at the MRL of 2 [mu]g/L (USEPA, 2006a and 2006b).

EPA also evaluated the results of a USGS review of 3 highway and urban runoff studies (Lopes and Dionne, 1998). These studies showed no detects for either 2,4- or 2,6-DNT using a reporting limit of 5 [mu]g/L (a value within the 10^{-4} to 10^{-6} risk range).

d. *Preliminary Determination.* The Agency has made a preliminary determination not to regulate 2,4- or 2,6-DNT with an NPDWR. Because 2,4- and 2,6-DNT appear to occur infrequently at levels of concern in PWSs, the Agency believes that a national primary drinking water regulation does not present a meaningful opportunity for health risk reduction. 2,4-DNT was detected only once at a minimum reporting level that is within the 10^{-4} to the 10^{-6} cancer risk range, while 2,6-DNT was not detected at this same level in any of the PWSs monitored under the UCMR 1.

EPA recognizes that 2,4- and 2,6-DNT are listed as probable human carcinogens. For this reason, the Agency encourages those States with public water systems that may have either 2,4- or 2,6-DNT above the HRL to evaluate site-specific protective measures and to consider whether State-level guidance (or some other type of action) is appropriate. The Agency's original Health Advisories for 2,4- and 2,6-DNT were developed for military installations. Because the Agency recognizes that 2,4- and 2,6-DNT may still be found at some military sites, the Agency has updated the Health Advisories to reflect recent health effects publications. The Health Advisories are available for review in the docket. The updated Health Advisories will provide information to any States with public water systems that may have either 2,4- or 2,6-DNT above the HRL.

8. s-Ethyl dipropylthiocarbamate (EPTC)

a. *Background.* EPTC, a synthetic organic compound, is a thiocarbamate herbicide used to control weed growth during the pre-emergence and early post-emergence stages of weed germination. First registered for use in 1958, EPTC is used across the U.S. in the agricultural production of a number of crops, most notably corn, potatoes, dried beans, alfalfa, and snap beans. EPTC is also used residentially on shade trees, annual and perennial ornamentals, and evergreens (USEPA, 1999c).

Estimates of EPTC usage in the United States suggest a decline from approximately 17 to 21 million pounds active ingredient in 1987 to approximately 7 to 9 million pounds active ingredient in 1999. TRI data from 1995 to 2003 indicate that most on-site industrial releases of EPTC tend to be releases to air and underground injections. Surface water discharges are

minimal in comparison (USEPA, 2006g). Total releases for 2003 were 2,183 lbs.

Environmental fate data indicate that EPTC would not be persistent under most environmental conditions. Volatilization into the atmosphere and degradation by soil organisms appear to be the primary dissipation routes. EPTC has a low affinity for binding to the soil so the potential to leach to ground water does exist. If EPTC reaches ground water, volatilization is less likely to occur (USEPA, 1999c).

b. *Health Effects.* In acute animal toxicity studies, EPTC was shown to be moderately toxic via oral and dermal routes and highly toxic via inhalation exposures. EPTC is a reversible cholinesterase (ChE) inhibitor. Similar to other thiocarbamates, it does not produce a consistent ChE inhibition profile. There was no consistent pattern observed in any of the toxicity studies with regard to species, duration of treatment, or the type of ChE enzyme measured. Typically, studies showed inhibition of plasma ChE with dose-related decreases in red blood cell and brain ChE activity. Some studies have shown that brain ChE activity was inhibited without any effect on either plasma or erythrocyte ChE activities. Other studies illustrated erythrocyte ChE inhibition with no effect on either plasma or brain ChE (USEPA, 1999c). In a primary eye irritation study in rabbits, technical grade EPTC was shown to be slightly irritating (USEPA, 1999c).

In subchronic and chronic studies performed in both rats and dogs, there was a dose-related increase in the incidence and severity of cardiomyopathy, a disorder of the heart muscle (Mackenzie, 1986; USEPA, 1999c). An increase in the incidence and severity of degenerative effects (neuronal and/or necrotic degeneration) in both the central and peripheral nervous system was observed in rats and dogs following exposure to EPTC (USEPA, 1999c).

EPA derived an RfD of 0.025 mg/kg/day for EPTC (USEPA, 1990d; USEPA, 1999c). This value was calculated using a NOAEL of 2.5 mg/kg/day from a study by Mackenzie (1986). An uncertainty factor of 100 was applied for inter- and intraspecies differences. The critical effect associated with the RfD is cardiomyopathy (disease of the heart muscle). In the reregistration of EPTC, the application of a ten-fold Food Quality Protection Act (FQPA) factor was recommended in order to be protective against residential exposures of infants and children. The Agency derived the HRL for EPTC using the RfD of 0.025 mg/kg/day and a 20 percent relative source contribution. The HRL is calculated to be 0.175 mg/L or 175 [mu]g/L.

The Agency used long-term studies in mice and rats and short-term studies of mutagenicity to evaluate the potential for carcinogenicity (USEPA, 1990d). Based on these data and using EPA's 1999 Guidelines for Carcinogen Risk Assessment, EPTC is not likely to be carcinogenic to humans (USEPA, 1999a).

EPA also evaluated whether health information is available regarding the potential effects on children and other sensitive populations. Data do not suggest increased pre- or post-natal sensitivity of children and infants to EPTC exposure. In animal studies, adverse developmental effects (i.e., decreased fetal body weight and decreased litter size) were only seen at doses that were toxic to the mother (USEPA, 1999c). Results from both developmental and reproductive studies indicate that there are only minimal adverse effects. The behavior patterns of children that lead to heightened opportunities for exposure in the indoor environment and the need for a developmental neurotoxicity study lead OPP to recommend the application of a ten-fold FQPA factor for EPTC. However, EPA did not apply this factor in the screening analysis because it does not apply to programs other than the pesticide registrations.

c. *Occurrence.* EPA included EPTC as an analyte in the UCMR 1. None of the 3,866 PWSs sampled (serving a population of 226 million) had detects of EPTC at the MRL of 1 [mu]g/L. Hence, these data indicate that no occurrence and exposure is expected at levels greater than 87.5 [mu]g/L (½ the HRL) and greater than 175 [mu]g/L (the HRL) (USEPA, 2006a and 2006b).

EPA also evaluated several sources of supplemental information, which included:

<bullet≤ The National Pesticide Survey,

<bullet≤ The Pesticides in Ground Water Database, and

<bullet≤ The provisional pesticide results from the 1992–2001 USGS NAWQA survey of ambient surface and ground waters across the U.S.

As part of the National Pesticide Survey, EPA collected samples from approximately 1,300 community water systems and rural drinking water wells between 1988 and 1990. The NPS included EPTC as an analyte in the monitoring survey. EPTC was not detected using a minimum reporting limit of 0.15 [mu]g/L (USEPA, 1990a).

The Pesticides in Ground Water Database (USEPA, 1992b) indicates that EPTC was found in 2 of 1,752 ground water wells that were sampled in 10 States. Both contaminated wells were in Minnesota. The detected concentrations ranged from 0.01 to 0.33 [mu]g/L. All of these positive detections are less than the HRL of 175 [mu]g/L, as well as 87.5 [mu]g/L (½ the HRL).

The USGS NAWQA program included EPTC as an analyte in its 1992–2001 monitoring survey of ambient surface and ground waters across the United States. EPA evaluated the results of the provisional data, which are available on the Web (Martin *et al.*, 2003; Kolpin and Martin, 2003). While the USGS detected EPTC in both surface and ground waters, 95 percent of the samples from the various land use settings were less than or equal to 0.018 [mu]g/L. The estimated maximum surface water concentration, 29.6 [mu]g/L (mixed land use settings), and the maximum ground water concentration, 0.45 [mu]g/L (agricultural settings), are both less than 175 [mu]g/L (the EPTC HRL).

d. *Preliminary Determination.* The Agency has made a preliminary determination not to regulate EPTC with an NPDWR. Because EPTC does not appear to occur at health levels of concern in PWSs, the Agency believes that a national primary drinking water regulation does not present a meaningful opportunity for health risk reduction. While EPTC has been found in ambient waters, it was detected only at levels less than the HRL (as well as ½ the HRL) and it was not found in the UCMR 1 survey of public water supplies.

9. Fonofos

a. *Background.* Fonofos, an organophosphate, is a soil insecticide used to control pests such as corn rootworms, cutworms, symphylans (i.e., garden centipedes), and wireworms. Primarily used on corn crops, fonofos was also used on other crops such as asparagus, beans, beets, corn, onions, peppers, tomatoes, cole crops, sweet potatoes, peanuts, peas, peppermint, plantains, sorghum, soybeans, spearmint, strawberries, sugarcane, sugar beets, white (Irish) potatoes, and tobacco (USEPA, 1999d).

Fonofos was scheduled for a reregistration decision in 1999. However, before the review was completed, the registrant requested voluntary cancellation. The cancellation was announced in the **Federal Register** on May 6, 1998 (63 FR 25033 (USEPA, 1998d)), with an effective date of November 2, 1998, plus a one-year grace period to permit the exhaustion of existing stocks (USEPA, 1999d).

NCFAP data indicate that fonofos use declined significantly during the 1990s (NCFAP, 2004). According to NCFAP,

approximately 3.2 million pounds of fonofos a.i. were applied annually around 1992 and approximately 0.4 million pounds a.i. were applied annually around 1997. The U.S. Geological Survey (USGS) estimates an average of 2.7 million pounds a.i. were used annually around 1992 (Thelin and Gianessi, 2000).

Fonofos is moderately persistent in soil and its persistence depends on soil type, organic matter, rainfall, and sunlight. Since fonofos adsorbs moderately well to soil, it is not readily leached or transported to ground water but it can be transported to surface waters in runoff. Fonofos is rapidly degraded by soil microorganisms (Extoxnet, 1993). Fonofos tends to volatilize from wet soil and water surfaces, but the process is slowed by adsorption to organic material in soil, suspended solids, and sediment (HSDB, 2004d).

b. *Health Effects.* Fonofos (like many organophosphates) is toxic to humans and animals. Case reports and acute oral toxicity studies in animals indicate that oral exposure to fonofos induces clinical signs of toxicity that are typical of cholinesterase inhibitors. In humans, accidental exposures produced symptoms of acute intoxication, nausea, vomiting, salivation, sweating, muscle twitches, decreased blood pressure and pulse rate, pinpoint pupils, profuse salivary and bronchial secretions, cardiorespiratory arrest, and even death in 1 exposed individual (Hayes, 1982; Pena Gonzalez *et al.*, 1996).

In animals, clinical signs of exposure included tremors, salivation, diarrhea, and labored breathing (USEPA, 1996c). Chronic exposure studies also indicated that oral administration of fonofos inhibits cholinesterase (Banerjee *et al.*, 1968; Cockrell *et al.*, 1966; Hodge, 1995; Horner, 1993; Miller, 1987; Miller *et al.*, 1979; Pavkov and Taylor, 1988; Woodard *et al.*, 1969). Cholinesterase inhibition is one of the critical effects associated with the RfD, which was verified by EPA (USEPA, 1991) at 0.002 mg/kg/day. EPA derived the RfD of 0.002 mg/kg/day using a NOAEL of 0.2 mg/kg/day (Hodge, 1995) and a 100-fold uncertainty factor to account for inter- and intraspecies differences.

Fonofos is classified as an unlikely human carcinogen (Group E) because there is no evidence of carcinogenic potential in the available long-term feeding studies in rats and mice (Banerjee *et al.*, 1968; Pavkov and Taylor, 1988; Sprague and Zwicker, 1987). In addition, fonofos does not appear to be mutagenic (USEPA, 1996c).

EPA evaluated whether health information is available regarding the potential effects on children and other sensitive populations. In the available developmental studies with rabbits (Sauerhoff, 1987) and mice (Minor *et al.*, 1982; Pulsford, 1991), no developmental effects were observed at oral doses as high as 1.5 mg/kg/day in the rabbit (highest dose tested) nor in mice at doses as high as 2.0 mg/kg/day (Minor *et al.*, 1982; Pulsford, 1991). However, in mice, effects were noted at higher dose levels. These effects included an increase in the incidence of variant sternebrae ossifications (at 6 mg/kg/day or greater) and a slight dilation of the fourth brain ventricle in offspring (at 4 mg/kg/day or greater). No developmental neurotoxicity study with fonofos is available for further assessment of this endpoint. In a three-generation reproduction study in rats (Woodard *et al.*, 1968), no treatment-related adverse effects were observed at the 2 dose levels used in this study, 0.5 and 1.58 mg/kg/day.

The Agency believes that the current RfD is adequately protective of children. The current fonofos RfD of 0.002 mg/kg/day is 1000-fold lower than the NOAEL observed in the Woodard *et al.* (1968) developmental studies.

Using the RfD of 0.002 mg/kg/day for fonofos and a 20 percent screening relative source contribution, the Agency derived an HRL of 0.014 mg/L and rounded to 0.01 mg/L (or 10 [mu]g/L).

c. *Occurrence.* EPA included fonofos as an analyte in the UCMR 1 List 2 Screening Survey. None of the 2,306 samples from the 295 PWSs sampled (serving a population of 41 million) contained detects for fonofos at the MRL of 0.5 [mu]g/L. Hence, these data indicate that no occurrence and exposure is expected at levels greater than 5 [mu]g/L (½ the HRL) and greater than 10 [mu]g/L (the HRL) (USEPA, 2006a and 2006b).

The USGS NAWQA program included fonofos as an analyte in its 1992–2001 monitoring survey of ambient surface and ground waters across the United States. EPA evaluated the results of the provisional data, which are available on the Web (Martin *et al.*, 2003; Kolpin and Martin, 2003). While the USGS detected fonofos in both surface and ground waters, 95 percent of the samples from the various land use settings were less than 0.003 [mu]g/L (the reporting limit). The maximum surface water concentration, 1.20 [mu]g/L (agricultural setting), and the maximum ground water concentration, 0.009 [mu]g/L (agricultural setting), are both less than 10 [mu]g/L and less than 5 [mu]g/L (the fonofos HRL and ½ the HRL).

d. *Preliminary Determination.* The Agency has made a preliminary determination not to regulate fonofos with an NPDWR. Because fonofos does not appear to occur at health levels of concern in PWSs, the Agency believes that a national primary drinking water regulation does not present a meaningful opportunity for health risk reduction. While fonofos has been found in ambient waters, it was detected only at levels less than the HRL (as well as ½ the HRL) and it was not found in UCMR 1 Screening Survey of public water supplies. Fonofos was voluntarily cancelled in 1998 and the Agency expects any remaining stocks and releases into the environment to decline. In addition, since fonofos tends to bind strongly to soil, any releases to the environment are not likely to contaminant source waters.

10. Terbacil

a. *Background.* Terbacil, a synthetic organic compound, is a selective herbicide used to control broadleaf weeds and grasses on terrestrial food/feed crops (e.g., apples, mint, peppermint, spearmint, and sugarcane), terrestrial food (e.g., asparagus, blackberry, boysenberry, dewberry, loganberry, peach, raspberry, youngberry, and strawberry), terrestrial feed (e.g., alfalfa, forage, and hay) and forest trees (e.g., cottonwood) (USEPA, 1998e).

In 1998, EPA estimated that agricultural usage of terbacil consumed approximately 221,000 to 447,000 pounds of active ingredient annually and non-agricultural usage consumed approximately 9,000 to 14,000 pounds. These estimates are based on data collected mostly between 1990 and 1995, and in some cases as early as 1987 (USEPA, 1998e). According to NCFAP (2004), approximately 298,000 pounds of terbacil a.i. were applied annually in agriculture around 1992 and approximately 342,000 pounds a.i. were applied around 1997.

Terbacil is listed as a TRI chemical and data are reported from one or more facilities in a single state, Texas, for the time period covering 1995 to 1997. During this three-year period, all reported releases were on-site releases to surface water that varied between 3,000 to 10,000 pounds annually (USEPA, 2006h).

Terbacil is considered a persistent and potentially mobile herbicide in terrestrial environments. Because of its low affinity to soils, it can potentially leach into ground and/or surface waters (USEPA, 1998e; Extoxnet, 1994).

b. *Health Effects.* In acute and subchronic toxicity studies, terbacil is practically non-toxic (Haskell Laboratories, 1965a and 1965b). Terbacil does not cause dermal sensitivity in

rabbits or guinea pigs and causes mild conjunctival eye irritation in rabbits (Henry, 1986; Hood, 1966). In rats exposed subchronically to dietary terbacil, effects were seen at a LOAEL of 25 mg/kg/day and included increased absolute and relative liver weights, vacuolization, and enlargement of liver cells (Wazeter *et al.*,1964; Haskell Laboratories, 1965c).

A primary target organ in rats following exposure to terbacil is the liver. Chronic effects of dietary terbacil exposure in two-year studies included increases in thyroid-to-body weight ratios, slight increases in liver weights and elevated alkaline phosphatase levels in beagle dogs, significant decreases in body weight in rats, increases in serum cholesterol levels and increases in liver to body weight ratios in rats (Wazeter *et al.*,1967a; Malek, 1993). In beagle dogs, effects were seen at or above 6.25 mg/kg/day (NOAEL = 1.25 mg/kg/day). In rats, effects (*i.e.*, decreases in body weight, increases in liver weights and cholesterol levels) were seen at higher levels (LOAELs = 56 mg/kg/day for males and 83 mg/kg/day for females).

Terbacil is not considered to be a developmental or reproductive toxicant. In developmental studies, maternal effects were generally seen prior to or at the same levels as developmental effects. Haskell Laboratories (1980) reported maternal effects (*i.e.*, decreased body weight) and significant decreases in the number of live fetuses per litter due to early fetal resorption at a LOAEL of 62.5 mg/kg/day in rats. In rabbits administered terbacil via gavage, the maternal and developmental LOAELs were equal (600 mg/kg/day). Maternal toxicity was based on the death of the dams and developmental toxicity was based on a decrease in live fetal weights (Solomon, 1984). No reproductive effects were seen in a three-generation study where terbacil was administered to male and female rats at dose levels of 2.5 and 12.5 mg/kg/day (Wazeter *et al.*, 1967b).

Terbacil is not mutagenic. Terbacil was tested and found negative in a chromosomal aberration study in rat bone marrow cells, found negative in a gene mutation assay (with and without S9 activation), and found negative for DNA synthesis when tested up to cytotoxic levels in rats (Cortina, 1984; Haskell Laboratories,1984). Terbacil shows no evidence of carcinogenicity and is unlikely to be carcinogenic to humans (Group E) (USEPA, 1998e).

The RfD of 0.013 mg/kg/day for terbacil (USEPA, 1998e) is calculated from a two-year chronic study in beagle dogs. The LOAEL of 6.25 mg/kg/day was based on increased thyroid-to-body weight ratios, slight increases in liver weights, and elevated alkaline phosphatase levels with a NOAEL of 1.25 mg/kg/day. In deriving the RfD, the Agency applied an uncertainty factor of 100 to account for interspecies and intraspecies differences. Using the RfD of 0.013 mg/kg/day and applying a 20 percent screening relative source contribution, the Agency derived an HRL of 0.090 mg/L (or 90 g/L) for terbacil.

EPA also evaluated whether health information is available regarding the potential effects on children and other sensitive populations. In the case of terbacil, the Agency determined that there was no need to apply an FQPA factor to the RfD in order to protect children (USEPA, 1998e). Other potentially sensitive subpopulations have not been identified.

c. *Occurrence.* EPA included terbacil as an analyte in UCMR 1. None of the 3,866 PWSs sampled (serving a population of 226 million) had detects for terbacil at the MRL of 2 g/L. Hence, these data indicate that no occurrence and exposure is expected at levels greater than 45 g/L (½ the HRL) and greater than 90 [mu]g/L (the terbacil HRL) (USEPA, 2006a and 2006b).

EPA also evaluated several sources of supplemental information, which included:

<bullet≤ The National Pesticide Survey,

<bullet≤ The Pesticides in Ground Water Database, and

<bullet≤ The provisional pesticide results from the 1992–2001 USGS NAWQA survey of ambient surface and ground waters across the U.S.

As part of the National Pesticide Survey, EPA collected samples from approximately 1,300 community water systems and rural drinking water wells between 1988 and 1990. The NPS included terbacil as an analyte in the monitoring survey. Terbacil was not detected using a minimum reporting limit of 1.7 [mu]g/L (USEPA, 1990a).

The Pesticides in Ground Water Database (USEPA, 1992b) indicates that terbacil was found in 6 of the 288 ground water wells tested for this contaminant in 6 States. Terbacil was found in 1 ground water well in Oregon (at a concentration of 8.9 [mu]g/L) and 5 ground water wells in West Virginia (with concentrations ranging from 0.3 to 1.2 [mu]g/L). All of the positive detections are less than the HRL of 90 [mu]g/L, as well as 45 [mu]g/L (½ the HRL).

The USGS NAWQA program included terbacil as an analyte in its 1992–2001 monitoring survey of ambient surface and ground waters across the United States. EPA evaluated the results of the provisional data, which are available on the Web (Martin *et al.*, 2003; Kolpin and Martin, 2003). While the USGS detected terbacil in both surface and ground waters, 95 percent of the samples from the various land use settings were less than 0.034 [mu]g/L (the USGS reporting limit). The maximum surface water concentration, 0.54 [mu]g/L (agricultural setting), and the maximum ground water concentration, 0.891 [mu]g/L (mixed land use setting), are both less than 90 [mu]g/L and less than 45 [mu]g/L (the terbacil HRL and ½ the HRL).

d. *Preliminary Determination.* The Agency has made a preliminary determination not to regulate terbacil with an NPDWR. Because terbacil does not appear to occur at health levels of concern in PWSs, the Agency believes that a national primary drinking water regulation does not present a meaningful opportunity for health risk reduction. Terbacil has been found in ambient waters but the levels were less than the HRL (as well as ½ the HRL). It was not found in the UCMR 1 survey of public water supplies.

11. 1,1,2,2-Tetrachloroethane

a. *Background.* 1,1,2,2-Tetrachloroethane, a volatile organic compound, is not known to occur naturally in the environment (IARC, 1979). Prior to the 1980s, 1,1,2,2-tetrachloroethane was synthesized for use in the production of other chemicals, primarily chlorinated ethylenes. 1,1,2,2-Tetrachloroethane was also once used as a solvent to clean and degrease metals, in paint removers, varnishes, lacquers, and photographic films, and for oil/fat extraction (Hawley, 1981). Commercial production of 1,1,2,2-tetrachloroethane in the U.S. ceased in the 1980s when other processes to generate chlorinated ethylenes were discovered (ATSDR, 1996).

Production of 1,1,2,2-tetrachloroethane in the U.S. was approximately 440 million pounds in 1967 (Konietzko, 1984). Production declined to an estimated 34 million pounds by 1974 (ATSDR, 1996). Although U.S. commercial production ceased in the 1980s, 1,1,2,2-tetrachloroethane is still generated as a byproduct and/or intermediate in the production of other chemicals. TRI data indicate that environmental releases have generally declined from a high of about 175,000 pounds in 1988 to a low of 3,500 pounds in 2003. Most releases took the form of air emissions, though surface water discharges were also documented nearly every year (USEPA, 2006i).

Volatilization from water or soil surfaces to the atmosphere appears to be the primary dissipation route for 1,1,2,2-tetrachloroethane. In subsurface soils and ground water, 1,1,2,2-tetrachloroethane is subject to biodegradation by soil organisms and/or chemical hydrolysis by water (ATSDR, 1996).

b. *Health Effects.* Data on the toxicity of 1,1,2,2-tetrachloroethane in humans are limited, consisting of one experimental inhalation study, a few case reports of suicidal or accidental ingestion, and dated occupational studies. In most cases, there was no quantification of the exposure. Respiratory and mucosal effects, eye irritation, nausea, vomiting, and dizziness were reported by human volunteers exposed to 1,1,2,2-tetrachloroethane vapors under controlled chamber conditions (Lehmann and Schmidt-Kehl, 1936). Effects from non-lethal occupational exposures included gastric distress (i.e., pain, nausea, vomiting), headache, loss of appetite, an enlarged liver, and cirrhosis (Jeney *et al.*, 1957; Lobo-Mendonca, 1963; Minot and Smith, 1921).

There have been a variety of animal studies in rats and mice using both the inhalation and oral exposure routes. Recent studies by the National Toxicology Program (NTP, 2004) provide a detailed evaluation of the short-term and subchronic oral toxicity of 1,1,2,2-tetrachloroethane and confirm many of the observations from earlier studies. In rats and mice exposed orally, the liver appears to be the primary target organ. The RfD (10 [mu]g/kg/day) for 1,1,2,2-tetrachloroethane was derived from the BMDL for a 1 standard deviation change in relative liver weight, a biomarker for liver toxicity. A 1,000-fold uncertainty factor was applied in the RfD determination.

A National Cancer Institute (1978) bioassay of 1,1,2,2-tetrachloroethane found clear evidence of carcinogenicity in male and female B6C3F1 mice based on a dose-related statistically significant increase in liver tumors. There was equivocal evidence for carcinogenicity in Osborn Mendel rats because of the occurrence of a small number of rare-for-the species neoplastic and preneoplastic lesions in the livers of the high dose animals. The Agency used the slope factor of 8.5×10^{-2} for the tumors in female mice to derive the HRL of 0.4 [mu]g/L for use in the analysis of the occurrence data for 1,1,2,2-tetrachloroethane. Information on the reproductive effects of 1,1,2,2-tetrachloroethane is limited. There is a single one-generation inhalation study that does not follow a standard methodology and examined a small number of rats (5 females and 7 males) exposed via inhalation to 1 dose (13.3 mg/m^3). There were no statistically significant differences in the percentage of females having offspring, number of pups per litter, average birth weight, sex ratio, or post natal offspring mortality (Schmidt *et al.*, 1972). Effects on sperm in male rats were seen after oral (27 mg/kg/day; NTP, 2004) and inhalation (13 mg/m^3; Schmidt *et al.*, 1972) exposures. Similar effects were seen in mice but at higher doses. Fetal toxicity did not occur in the absence of maternal toxicity.

Developmental range-finding studies conducted for NTP (1991a and b) found that 1,1,2,2-tetrachloroethane was toxic to the dams and pups of Sprague Dawley rats and CD–1 Swiss mice. Rats were more sensitive than mice. The NOAEL in the rats for both maternal toxicity and associated fetal toxicity was 34 mg/kg/day with a LOAEL of 98 mg/kg/day. In mice, the NOAEL was 987 mg/kg/day and the LOAEL was 2,120 mg/kg/day.

EPA also evaluated whether health information is available regarding the potential effects on children and other sensitive populations. Individuals with preexisting liver and kidney damage would likely be sensitive to 1,1,2,2-tetrachloroethane exposure. Low intake of antioxidant nutrients (e.g., Vitamin E, Vitamin C, and selenium) could be a predisposing factor for liver damage. In addition, individuals with a genetically low capacity to metabolize dichloroacetic acid (the primary metabolite of 1,1,2,2-tetrachloroethane) may be at greater risk than the general population as a result of 1,1,2,2-tetrachloroethane exposure.

c. *Occurrence.* EPA included 1,1,2,2-tetrachloroethane as an analyte in the UCM Round 1 and UCM Round 2 surveys. EPA evaluated the UCM Round 1 Cross Section and the UCM Round 2 Cross Section data at levels greater than 0.2 [mu]g/L (½ the HRL) and greater than 0.4 [mu]g/L (the HRL) (USEPA, 2006a and 2006c). The MRLs for UCM Round 1 ranged from 0.1 to 10 [mu]g/L and the MRLs for UCM Round 2 ranged from 0.1 to 2.5 [mu]g/L. Because some of the reporting limits exceeded the thresholds of interest, the occurrence analyses may result in an underestimate of systems affected. However, all the MRL values used for UCM Round 1 and UCM Round 2 are within the 10^{-4} to the 10^{-6} cancer risk range.

Analysis of UCM Round 1 Cross Section data indicates that approximately 0.22 percent (or 44) of the 20,407 PWSs sampled had detections of 1,1,2,2-tetrachloroethane at levels greater than 0.20 [mu]g/L (½ the HRL), affecting approximately 1.69 percent of the population served (or 1.6 million of 95 million). The UCM Round 1 Cross Section data indicate that approximately 0.20 percent (or 41) of the 20,407 PWSs sampled had detections of 1,1,2,2-tetrachloroethane at levels greater than 0.4 [mu]g/L (the HRL), affecting approximately 1.63 percent of the population served (or 1.5 million of 95 million). The 99th percentile of all detects is 112 [mu]g/L and the maximum reported value is 200 [mu]g/L.

Analysis of the UCM Round 2 Cross Section data indicate that approximately 0.07 percent (or 18) of the 24,800 PWSs sampled had detections of 1,1,2,2-tetrachloroethane at levels greater than 0.2 [mu]g/L (½ the HRL), affecting approximately 0.51 percent of the population served (or 362,000 of 71 million). The UCM Round 2 Cross Section data indicate that approximately the same percentage and number of the PWSs sampled (0.07 percent or 17 of the 24,800) had detections of 1,1,2,2-tetrachloroethane at levels greater than 0.4 [mu]g/L (the HRL), affecting approximately 0.08 percent of the population served (or 56,000 of 71 million). The 99th percentile of all detects is 2 [mu]g/L and the maximum reported value is 2 [mu]g/L.

EPA also evaluated several sources of supplemental information, which included the USGS VOC National Synthesis Random Source Water Survey and the Focused Source Water Survey. For the Random Source Water Survey, the USGS collected samples from 954 source waters that supply community water systems between 1999 and 2000. For the Focused Source Water Survey, the USGS collected 451 samples from 134 source waters that supply community water systems between 1999 and 2001. The USGS included 1,1,2,2-tetrachloroethane as an analyte in both surveys and did not detect it in any of the source water samples using a reporting limit of 0.2 [mu]g/L (a level that is less than the 1,1,2,2-tetrachloroethane HRL). In addition, USGS did not detect 1,1,2,2-tetrachloroethane when using a detection level of 0.026 [mu]g/L (a level that is over 10 times lower than the 1,1,2,2-tetrachloroethane HRL) in the focused survey (Ivahnenko *et al.*, 2001, Grady, 2003, Delzer and Ivahnenko, 2003a).

d. *Preliminary Determination.* The Agency has made a preliminary determination not to regulate 1,1,2,2-tetrachloroethane with an NPDWR. Because 1,1,2,2-tetrachloroethane appears to occur infrequently at health levels of concern in PWSs, the Agency

believes that a national primary drinking water regulation does not present a meaningful opportunity for health risk reduction. While 1,1,2,2-tetrachloroethane was detected in both the UCM Round 1 and the UCM Round 2 surveys, the percentage of detections had decreased by the time the UCM Round 2 survey was performed in the mid-1990's. In addition, the USGS did not detect 1,1,2,2-tetrachloroethane in two subsequent monitoring surveys of source waters that supply community water systems using a reporting limit that is less than the 1,1,2,2-tetrachloroethane HRL. The Agency believes that this decrease in detections occurred because commercial production of 1,1,2,2-tetrachloroethane ceased in the mid-1980's. Hence, the Agency does not expect 1,1,2,2-tetrachloroethane to occur in many public water systems today.

EPA recognizes that 1,1,2,2-tetrachloroethane is listed as a likely human carcinogen. For this reason, the Agency encourages those States with public water systems that may have 1,1,2,2-tetrachloroethane above the HRL to evaluate site-specific protective measures and to consider whether State-level guidance (or some other type of action) is appropriate. The Agency also plans to update the Health Advisory document for 1,1,2,2-tetrachloroethane to provide more recent health information. The updated Health Advisory will provide information to any States with public water systems that may have 1,1,2,2-tetrachloroethane at levels above the HRL.

V. What Is the Status of the Agency's Evaluation of Perchlorate?

At this time, the Agency is not making a preliminary determination as to whether a national primary drinking water regulation is needed for perchlorate. However, the Agency has placed a high priority on making a regulatory determination for perchlorate and will publish a preliminary determination as soon as possible. EPA is not able to make a preliminary determination at this time because, in order to evaluate perchlorate against the three SDWA statutory criteria, the Agency believes additional information may be needed to more fully characterize perchlorate exposure and determine whether regulating perchlorate in drinking water presents a meaningful opportunity for health risk reduction. This is particularly true if the Agency uses food exposure data to first calculate a relative source contribution (RSC) and corresponding health reference level (HRL) below the drinking water equivalent level (DWEL) [18] in order to determine whether regulating perchlorate would present a meaningful opportunity for health risk reduction. However, the Agency is considering several other approaches, discussed below, for making this statutory determination and is requesting public comment on the strengths and limitations of these approaches.

The following sections explain why EPA is not making a preliminary regulatory determination for perchlorate at this time, and discusses the information the Agency has collected to date (that may be relevant to making a preliminary regulatory determination), the additional information the Agency is soliciting in this action, and options for additional analyses that the Agency may conduct to support a regulatory determination. Sections V.A through V.D provide a summary of the available and relevant information/data that the Agency has collected and reviewed regarding the sources of perchlorate in the environment, its potential health effects, and its occurrence in drinking water, food, human urine, breast milk, and amniotic fluid. Section V.E explains the Agency's basis for not making a preliminary regulatory determination for perchlorate at this time and Section V.F. presents the options the Agency is considering to better characterize perchlorate exposure and the alternate approaches that EPA is considering for making a preliminary regulatory determination. This action provides an opportunity for the public to submit other relevant data that may further characterize exposure to perchlorate through the consumption of foods and/or through other pathways and to comment on these alternate approaches. The Agency in particular seeks comment on the use of urine biomonitoring data in estimating perchlorate exposure. The Agency will consider any relevant information/data provided in response to this action as the Agency determines whether to regulate perchlorate with a national primary drinking water regulation and how best to proceed to address perchlorate.

A. Sources of Perchlorate

Perchlorate (ClO_4^-) is an anion commonly associated with the solid salts of ammonium, magnesium, potassium, and sodium perchlorate. Perchlorate salts are highly soluble in water, and because perchlorate sorbs poorly to mineral surfaces and organic material, perchlorate can be mobile in surface and subsurface aqueous environments. Although commonly known as a man-made chemical, perchlorate also may be derived from natural processes.

While perchlorate has a wide variety of industrial uses, it is primarily used in the form of ammonium perchlorate as an oxidizer in solid fuels used to power rockets, missiles, and fireworks. Approximately 90 percent of perchlorate is manufactured for this application (Wang *et al.*, 2002). Perchlorate can also be present as an ingredient or as an impurity in road flares, lubricating oils, matches, aluminum refining, rubber manufacturing, paint and enamel manufacturing, leather tanning, paper and pulp processing (as an ingredient in bleaching powder), and as a dye mordant.

Perchlorate can also occur naturally in the environment. Chile possesses caliche ores rich in sodium nitrate ($NaNO_3$), which are also a natural source of perchlorate (Schilt, 1979 and Ericksen, 1983). These Chilean nitrate salts (saltpeter) have been mined and refined to produce commercial fertilizers, which before 2001 accounted for about 0.14 percent of U.S. fertilizer application (USEPA, 2001d). The USEPA (2001d) conducted a broad survey of fertilizers and other raw materials and found that all products surveyed were devoid of perchlorate except for those known to contain or to be derived from mined Chilean saltpeter.

Perchlorate has also been found in other geologic materials. Orris *et al.* (2003) measured perchlorate at levels exceeding 1,000 parts per million (ppm or mg/kg) in several samples of natural minerals, including potash ore from New Mexico and Saskatchewan (Canada), playa crust from Bolivia, and hanksite from California.

Texas Tech University Water Resources Center conducted a large-scale sampling program to determine the source and distribution of perchlorate in northwest Texas groundwater (Jackson *et al.*, 2004; Rajagopalan *et al.*, 2006). Perchlorate was detected at concentrations greater than 0.5 g/L in 46 percent of public wells and 47 percent of private wells. Jackson *et al.* (2004) hypothesized that atmospheric production and/or surface oxidative weathering is the source of the perchlorate. In related research, Dasgupta *et al.* (2005) detected perchlorate in many rain and snow samples and demonstrated that perchlorate is formed by a variety of simulated atmospheric processes suggesting that natural, atmospherically-

[18] DWEL = [(Reference Dose x Body Weight of 70 kg) / Drinking Water Intake of 2 L per day].

derived perchlorate exists in the environment. Barron *et al.* (2006) developed a method for the rapid determination of perchlorate in rainwater samples, with a detection limit between 70 and 80 ng/L. Of the ten rainwater samples collected in Ireland in 2005, perchlorate was detected in 4 samples at concentrations between 0.075 and 0.113 g/L, and in 1 other sample at 2.8 g/L. Kang *et al.* (2006) conducted seven-day experiments to determine if it was possible to produce perchlorate by exposing various chlorine intermediates to UV radiation in the form of high intensity UV lamps and/or ambient solar radiation. Perchlorate formation was demonstrated in aqueous salt solutions with initial concentrations of hypochlorite, chlorite, or chlorate between 100 and 10,000 mg/L.

After a limited investigation, the Massachusetts Department of Environmental Quality (MA DEP, 2005) found that perchlorate may be present in sodium hypochlorite solutions used in water and wastewater treatment plants, and that the level of occurrence depends upon storage conditions and the initial purity of the stock solution (MA DEP, 2005). According to MA DEP (2005), the Town of Tewksbury conducted a small study to evaluate the impact of storage conditions (temperature and light) on a new shipment of sodium hypochlorite stock solution. Tewksbury found that the perchlorate concentration in the new stock solution increased from 0.2 g/L to levels ranging from 995 to 6,750 g/L depending on the storage conditions. Accounting for the large dilution factor (*e.g.*, 20,000 to 1 ratio) used in chlorination processes at drinking water treatment plants, MA DEP (2005) concluded that ''absent additional efforts to minimize breakdown of hypochlorite solutions, it would appear that low levels of the perchlorate ion (0.2 to 0.4 g/L) detected in a drinking water supply disinfected with sodium hypochlorite solutions could be attributable to the chlorination process.''

It is not clear at this time what proportion of perchlorate found in public water supplies or entering the food chain comes from these various anthropogenic and natural sources. The significance of different sources probably varies regionally. A study by Dasgupta *et al.* (2006) analyzes the three principal sources of perchlorate and their relative contributions to the food chain. These are its use as an oxidizer including rocket propellants, Chilean nitrate used principally as fertilizer, and that produced by natural atmospheric processes.

B. Health Effects

Perchlorate can interfere with the normal functioning of the thyroid gland by competitively inhibiting the transport of iodide into the thyroid. Iodide is an important component of two thyroid hormones, T4 and T3, and the transfer of iodide from the blood into the thyroid is an essential step in the synthesis of these two hormones. Iodide transport into the thyroid is mediated by a protein molecule known as the sodium (Na+)—iodide (I-) symporter (NIS). NIS molecules bind iodide with very high affinity, but they also bind other ions that have a similar shape and electric charge, such as perchlorate. The binding of these other ions to the NIS inhibits iodide transport into the thyroid, which can result in intrathyroidal iodide deficiency and consequently decreased synthesis of T4 and T3. There is compensation for iodide deficiency, however, such that the body maintains the serum concentrations of thyroid hormones within narrow limits through feedback control mechanisms. This feedback includes increased secretion of thyroid stimulating hormone (TSH) from the pituitary gland, which has among its effects the increased production of T4 and T3 (USEPA, 2005e). Sustained changes in thyroid hormone and TSH secretion can result in thyroid hypertrophy and hyperplasia (abnormal growth or enlargement of the thyroid) (USEPA, 2005e).

In January 2005, the National Research Council (NRC) of the National Academies of Science (NAS) published ''Health Implications of Perchlorate Ingestion,'' a review of the current state of the science regarding potential adverse health effects of perchlorate exposure and mode-of-action for perchlorate toxicity (NRC, 2005). Based on recommendations of the NRC, EPA chose data from the Greer *et al.* (2002) human clinical study as the basis for deriving a reference dose (RfD) for perchlorate (USEPA, 2005e). Greer *et al.* (2002) report the results of a well-controlled study that measured thyroid iodide uptake, hormone levels, and urinary iodide excretion in a group of 24 healthy adults administered perchlorate doses orally over a period of 14 days. Dose levels ranged from 0.007 to 0.5 mg/kg/day in the different experimental groups. No significant differences were seen in measured serum thyroid hormone levels (T3, T4, total and free) in any dose group. The statistical no observed effect level (NOEL) for perchlorate-induced inhibition of thyroid iodide uptake was 0.007 mg/kg/day. Although the NRC committee concluded that hypothyroidism is the first adverse effect in the continuum of effects of perchlorate exposure, NRC recommended that ''the most health-protective and scientifically valid approach'' was to base the perchlorate RfD on the inhibition of iodide uptake by the thyroid (NRC, 2005). NRC concluded that iodide uptake inhibition, although not adverse, is the key biochemical event in the continuum of possible effects of perchlorate exposure and would precede any adverse health effects of perchlorate exposure. The lowest dose (0.007 mg/kg/day) administered in the Greer *et al.* (2002) study was considered a NOEL (rather than a NOAEL) because iodide uptake inhibition is not an adverse effect but a biochemical change (USEPA, 2005e). A summary of the data considered and the NRC deliberations can be found in the NRC report (2005) and the EPA Integrated Risk Information System (IRIS) summary (USEPA, 2005e).

The NRC recommended that EPA apply an intraspecies uncertainty factor of 10 to the NOEL to account for differences in sensitivity between the healthy adults in the Greer *et al.* (2002) study and the most sensitive population, fetuses of pregnant women who might have hypothyroidism or iodide deficiency. Because the fetus depends on an adequate supply of maternal thyroid hormone for its central nervous system development during the first trimester of pregnancy, iodide uptake inhibition from low-level perchlorate exposure has been identified as a concern in connection with increasing the risk of neurodevelopmental impairment in fetuses of high-risk mothers (NRC, 2005). The NRC (2005) viewed the uncertainty factor of 10 as conservative and health protective given that the point of departure is based on a non-adverse effect (iodide uptake inhibition) that precedes the adverse effect in a continuum of possible effects of perchlorate exposure. NRC concluded that no uncertainty factor was needed for the use of a less-than chronic study, for deficiencies in the database, or for interspecies variability. To protect the most sensitive human population from chronic perchlorate exposure, EPA derived an RfD of 0.0007 mg/kg/day with a ten-fold total uncertainty factor from the NOEL of 0.007 mg/kg/day (USEPA, 2005e).

Blount *et al.* (2006b) recently published a study examining the relationship between urinary levels of perchlorate and serum levels of TSH and total T4 in 2,299 men and women (ages 12 years and older), who participated in CDC's 2001–2002

National Health and Nutrition Examination Survey (NHANES).[19] Blount *et al.* (2006b) evaluated perchlorate along with covariates known or likely to be associated with T4 or TSH levels to assess the relationship between perchlorate and these hormones, and the influence of other factors on this relationship. These covariates included sex, age, race/ethnicity, body mass index, serum albumin, serum cotinine (a marker of tobacco smoke exposure), estimated total caloric intake, pregnancy status, post-menopausal status, premenarche status, serum C-reactive protein, hours fasting before sample collection, urinary thiocyanate, urinary nitrate, and use of selected medications. The study found that perchlorate was a significant predictor of thyroid hormones in women, but not men. After finding evidence of gender differences, the researchers focused on further analyzing the NHANES data for the 1,111 women participants. They divided these 1,111 women into two categories, higher-iodide and lower-iodide, using a cut point of 100 [mu]g/L of urinary iodide based on the World Health Organization (WHO) definition of sufficient iodide intake.[20] Hypothyroid women were excluded from the analysis. According to the study authors, about 36 percent of women living in the United States have urinary iodide levels less than 100 [mu]g/L (Caldwell *et al.*, 2005). For women with urinary iodide levels less than 100 [mu]g/L, the study found that urinary perchlorate is associated with a decrease in (a negative predictor for) T4 levels and an increase in (a positive predictor for) TSH levels. For women with urinary iodide levels greater than or equal to 100 [mu]g/L, the researchers found that perchlorate is a significant positive predictor of TSH but not a predictor of T4. The study found that perchlorate was not a significant predictor of T4 or TSH in men. The researchers state that perchlorate could be a surrogate for another unrecognized determinant of thyroid function. Also, the study reports that while large doses of perchlorate are known to decrease thyroid function, this is the first time an association of decreased thyroid function has been observed at these low levels of perchlorate exposure. Of note is that the vast majority of the participants in this group had urinary levels of perchlorate corresponding to estimated dose levels that are below the RfD of 0.0007 mg/kg/day. The clinical significance of the variations in T4/TSH levels, which were generally within normal limits, has not been determined. The researchers noted several limitations of the study (e.g., assumption that urinary perchlorate correlates with perchlorate levels in the stroma and tissue and preference for measurement of free T4 as opposed to total T4) and recommended that these findings be confirmed in at least one more large study focusing on women with low urine iodide levels. It is also not known whether the association between perchlorate and thyroid hormone levels is causal or mediated by some other correlate of both, although the relationship between urine perchlorate and total TSH and T4 levels persisted after statistical adjustments for some additional covariates known to predict thyroid hormone levels (e.g., total kilocalorie intake, estrogen use, and serum C-reactive protein levels). A planned follow-up study will include additional measures of thyroid health and function (e.g., TPO-antibodies, free T4). As EPA proceeds towards a regulatory determination for perchlorate, the Agency will continue to review any new findings/studies on perchlorate and their relationship to thyroid function as they become available.

C. Occurrence in Water, Food, and Humans

1. Sources of Perchlorate. Section V.A. summarizes the potential sources of perchlorate in the environment.

2. Studies on Perchlorate Occurrence in Public Drinking Water Systems and/or Drinking Water Sources. EPA included perchlorate as an analyte in the 1999 Unregulated Contaminant Monitoring Regulation (UCMR 1) and collected drinking water occurrence data for perchlorate from 3,858 public water systems (PWSs) between 2001 and 2005. EPA analyzed the available UCMR 1 data on perchlorate at concentrations greater than or equal to 4 [mu]g/L, the minimum reporting limit (MRL) for EPA Method 314.0.[21] The Agency found that approximately 4.1 percent (or 160) of 3,858 PWSs that sampled and reported under UCMR 1 had at least 1 analytical detection of perchlorate (in at least 1 entry/sampling point) at levels greater than or equal to 4 [mu]g/L. These 160 systems are located in 26 states and 2 territories. Of these 160 PWSs, 8 are small systems (serving 10,000 or fewer people) and 152 are large systems (serving more than 10,000 people). Approximately 1.9 percent (or 637) of the 34,193 samples collected (by these 3,858 PWSs) had positive detections of perchlorate at levels greater than or equal to 4 [mu]g/L. The maximum reported concentration of perchlorate was 420 [mu]g/L, which was found in a surface water sample from a PWS in Puerto Rico. The average concentration of perchlorate for those samples with positive detections for perchlorate was 9.85 [mu]g/L and the median concentration was 6.40 [mu]g/L.

These 160 PWSs (with at least 1 analytical detection for perchlorate at levels greater than or equal to 4 [mu]g/L) serve approximately 7.5 percent (or 16.8 million) of the 225 million people served by the 3,858 PWSs that sampled and reported results under UCMR 1. The 16.8 million population-served value represents the total number of people served by the 160 PWSs with at least one detect. Not all people served by these systems necessarily have perchlorate in their drinking water. Some of these 160 public water systems have multiple entry points to the distribution system and not all of the entry points sampled had positive detections for perchlorate in the UCMR 1 survey. An alternative approach to the system-level assessment of populations served is to use an assessment at the entry (sampling) point level.[22] EPA does not have population-served values for each entry point at the system level. However, an assessment can be performed by assuming that each entry (or sampling) point at a public water system serves an equal proportion of the total population-served by the system. In other words, for the alternative assessment, the population served by each system is assumed to be equally distributed across all entry (or sampling) points at each system. For example, if a system serves a million people and has 5 entry points, it is assumed that each entry point serves 200,000 people. Using this approach and counting only

[19] While CDC researchers measured urinary perchlorate concentration for 2,820 NHANES participants, TSH and total T4 serum levels were only available for 2,299 of these participants.

[20] WHO notes that the prevalence of goiter begins to increase in populations with a median iodide intake level below 100 [mu]g/L (WHO, 1994).

[21] EPA Method 314.0 was the analytical method approved and used for UCMR 1 at the time of data collection.

[22] EPA acknowledges that uncertainties exist in the population-served estimates for this alternative assessment since the population for a system is assumed to be equally distributed across the entry points for that system. Because the actual population-served by an entry point is not known, this alternative approach has an equal chance of underestimating or overestimating the actual population-served by entry points with positive detections for perchlorate. In addition, this approach could underestimate the population served that is potentially exposed to perchlorate and overestimate the level of exposure because it can not incorporate the effects of mixing of water between different entry points within the distribution system. This is because the approach cannot account for the dilution that may occur when water that has no detections of perchlorate is mixed within the distribution system with water that has positive detections for perchlorate.

the population served for the entry points with positive detections (concentrations greater than or equal to 4 [mu]g/L), the total population served by these entry points with perchlorate detections is approximately 5 million. Section V.E provides the number of systems and population-served estimates for other thresholds of interest.

The California Department of Health Services (CA DHS) began monitoring for perchlorate in 1997. In 1999, CA DHS began requiring monitoring for perchlorate for drinking water sources that were identified as vulnerable to perchlorate contamination under California's own State monitoring program (i.e., Unregulated Chemicals for which Monitoring is Required). About 60 percent (or 7,100) of all drinking water sources in California (about 12,000) were monitored for perchlorate under the State monitoring program. Between June 2001 and June 2006, CA DHS (2006) reports that 284 (about 4%) of the approximately 7,100 water sources that monitored had at least 2 or more positive detections for perchlorate at concentrations greater than or equal to 4 [mu]g/L (the reporting limit). These 284 sources supply water for 77 drinking water systems (CA DHS, 2006) and represent active and standby sources (and exclude inactive, destroyed, and abandoned sources, and monitoring and agricultural wells) (CA DHS, 2006).

In 2005, the State of Massachusetts's Department of Environment Protection (MA DEP) reported monitoring results for 85 percent (379 of 450) of its community water systems and 86 percent (212 of 250) of its non-transient, non-community water systems. MA DEP found that 9 (1.5%) of the 591 public water systems detected perchlorate at levels greater than or equal to 1 [mu]g/L (the reporting limit used for a modified version of EPA Method 314.0). MA DEP found that the occurrence of perchlorate for these water systems could be traced to the use of blasting agents, military munitions, fireworks, and, to a lesser degree, sodium hypochlorite disinfectant (MA DEP, 2005).

3. Studies on Perchlorate Occurrence in Foods, Plants, Beverages, and Dietary Supplements. The Food and Drug Administration (FDA), the United States Department of Agriculture (USDA), and researchers from academia and industry have studied perchlorate in foods. Some of these studies are described briefly in this section, and also summarized in Table 4. EPA has concluded that the sampling results described in this section and Table 4 are too limited to characterize food-borne exposure to perchlorate on a national scale. The sampling data are limited in the types of foods sampled, sample sizes, geographic coverage, and/or analytical method adequacy and many were targeted to foods or areas known or likely to have elevated levels of perchlorate. Section V.F of this action describes the limitations of the food sampling data and also describes plans for including perchlorate as part of the FDA's Total Diet Study. EPA requests that commenters provide the Agency with any additional data that may further characterize the concentrations of perchlorate in foods commercially available in the U.S. When providing data to the Agency, please describe the specific locations where the samples were collected, including geographic location, type of location (e.g., grocery store, farmer's market, commercial field, home garden), and the methodologies used to select, collect, prepare, and analyze the samples. Please include available laboratory data reports as well as all relevant quality assurance/quality control information.

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Table 4. Summary Data on Perchlorate Occurrence in Food Items

Food Item	Data Reference	Units	N	MRL	Range of Detections	Reported Mean[a]	Rate of Detection (percent)	Sample Locations
Iceberg Lettuce	FDA (2004)[a]	µg/kg FW	38	1	<MRL – 71.6	7.76	79%[b]	AZ, CA, FL, NJ
	Sanchez *et al.* (2005a)[c]	µg/kg FW	44	~20	<MRL - 26	NA	86%	AZ, CA
	Sanchez *et al.* (2005a)[f]	µg/kg FW	24	25-30	ND - 24	10	NA	AZ, CA
	Sanchez *et al.* (2005b)[f]	µg/kg FW	63	20-40	ND - 31	7.4	NA	See note[m]
Romaine Lettuce	FDA (2004)[a]	µg/kg FW	40	1	<MRL - 129	11.9	95%[b]	AZ, CA, FL, NJ, TX
	Sanchez (2004)[e]	µg/kg FW	7	20 - 50	<MRL - 81	NA	100%	AZ, CA
	Sanchez *et al.* (2005a)[d]	µg/kg FW	24	25-30	ND - 20	13	NA	AZ, CA
	Sanchez *et al.* (2005b)[e]	µg/kg FW	84	20-40	ND - 100	17.1	NA	See note[m]
Green Leaf Lettuce	FDA (2004)[a]	µg/kg FW	25	1	1.00– 27.4	10.7	100%	AZ, CA, NJ, TX
	Sanchez (2004)[e]	µg/kg FW	3	20 - 50	46-64	NA	100%	AZ, CA
	Sanchez *et al.* (2005a)[e]	µg/kg FW	24	25-30	ND - 102	33	NA	AZ, CA
	Sanchez *et al.* (2005b)[e]	µg/kg FW	69	20-40	ND - 195	16.5	NA	See note[m]
Red Leaf Lettuce	FDA (2004)[a]	µg/kg FW	25	1	<MRL – 52.0	11.6	92%[b]	AZ, CA, TX
	Sanchez *et al.* (2005a)[e]	µg/kg FW	24	25-30	ND - 81	27	NA	AZ, CA
	Sanchez *et al.* (2005b)[e]	µg/kg FW	67	20-40	ND - 104	14.5	NA	See note[m]
Butterhead Lettuce	Sanchez *et al.* (2005a)[e]	µg/kg FW	24	25-30	ND - 104	29	NA	AZ, CA
	Sanchez *et al.* (2005b)[e]	µg/kg FW	45	20-40	ND - 98	17.2	NA	See note[m]
Arugula	Sanchez *et al.* (2005b)[e]	µg/kg FW	9	20-40	ND - 195	55.8	NA	See note[m]
Spinach	Sanchez *et al.* (2005b)[e]	µg/kg FW	10	20-40	ND - 628	85.1	NA	See note[m]
Bottled Water	FDA (2004)	µg/L	51	0.5	<MRL – 0.56	NA	4%[b]	CA, CO, GA, MD, MN, MO, NC, NE, PA, SC, TX, WI
Dairy Milk	FDA (2004)	µg/L	104	3	<MRL – 11.3	5.76	97%[b]	AZ, CA, GA, KS, LA, MD, MO, NJ, NC, PA, SC, TX, VA, WA
	Kirk *et al.* (2005)	µg/L	47	~1[g]	ND – 11.0	2.0	98%	AK, AZ, CA, FL, HI, KS, ME, NH, NM, NY, PA
	Kirk *et al.* (2003)	µg/L	7	0.5[g]	1.7 – 6.4	NA	100%	TX
Melon	Sanchez (2004)[h]	µg/kg FW	25	20 - 50	ND - <MRL	NA	48%	AZ, CA
	Jackson *et al.* (2005)[i]	µg/kg FW	1	NA	1600	NA	100%	KS

Table 4. Summary Data on Perchlorate Occurrence in Food Items

Food Item	Data Reference	Units	N	MRL	Range of Detections	Reported Mean[s]	Rate of Detection (percent)	Sample Locations
Cucumber	Jackson *et al.* (2005)[n]	µg/kg FW	2	NA	40 - 770	NA	100%	TX, KS
Tomato	Sanchez (2004)	µg/kg FW	8	20 - 50	ND - <MRL	NA	37%	AZ, CA
	Jackson *et al.* (2005)	µg/kg FW	2	NA	42 - 220	NA	100%	KS
Pepper	Sanchez (2004)	µg/kg FW	10	20 - 50	ND - <MRL	NA	30%	AZ, CA
Carrot	Sanchez (2004)	µg/kg FW	10	20 - 50	ND	NA	0%	CA
Onion	Sanchez (2004)	µg/kg FW	10	20 - 50	ND	NA	0%	CA
Sweet Corn	Sanchez (2004)	µg/kg FW	18	20 - 50	ND	NA	0%	AZ, CA
Squash	Sanchez (2004)	µg/kg FW	10	20 - 50	ND	NA	0%	AZ, CA
Wheat	Sanchez (2004)[j]	µg/kg FW	NA	20 - 50	ND	NA	0%	AZ
	Jackson *et al.* (2005)[k]	µg/kg FW	12	NA	710 – 4400[l]	NA	100%	TX
Alfalfa	Sanchez (2004)[o]	µg/kg FW	10	20 - 50	109 - 668	NA	100%	AZ, CA
	Jackson *et al.* (2005)[p]	µg/kg FW	3	NA	NA	2900	100%	TX
Soy Milk	Kirk *et al.* (2005)	µg/L	1	~1[g]	0.7	NA	100%	TX
Lemon	Sanchez *et al.* (2006)	µg/kg FW	33	~2.5	ND – 14.8	2.3	NA	AZ, CA
Grapefruit	Sanchez *et al.* (2006)	µg/kg FW	15	~2.5	ND – 16.2	3.3	NA	AZ, CA
Orange	Sanchez *et al.* (2006)	µg/kg FW	28	~2.5	ND – 37.6	7.4	NA	AZ, CA
Seaweed	Martinelango *et al.* (2006a)[q]	µg/kg DW	13	NA	29 - 878	NA	100%	Atlantic Ocean (ME)
Beer	Aribi *et al.* (2006)	µg/L	144	NA	0.005 – 21.096	NA	100%	47 countries (including USA)
	Aribi *et al.* (2006)	µg/L	8	NA	0.364 – 2.014	0.662[r]	100%	USA
Wine	Aribi *et al.* (2006)	µg/L	77	NA	0.029 – 50.25	NA	100%	22 countries (including USA)
	Aribi *et al.* (2006)	µg/L	12	NA	0.197 – 4.593	2.09[r]	100%	USA

Notes:
N = number of samples; MRL = minimum reporting limit; ND = not detected; FW = fresh weight; DW = dry weight; NA = not available from (or not appropriate for) the cited study.
[a] Outermost leaves of each lettuce head were removed prior to sample analysis.
[b] Rate of detection is based on number of samples for which perchlorate was quantifiable (not just detectable).
[c] Samples are of "edible head" (trimmed of frame and wrapper leaves).
[d] Samples are "bulk" (partial removal of stem core and partial severing of upper and outer leaf blade margins).
[e] Samples preparation included minimal trimming.
[f] Samples have had multiple layers of their outer wrapper leaves removed
[g] Value reported as the "limit of detection."
[h] Samples include cantaloupe, casaba, honey dew, galia, and watermelon.
[i] Sample of cantaloupe from a home garden in Morris County, KS.
[j] Durum wheat.
[k] Whole wheat head, including seed (endosperm), bran, germ, and chaff.
[l] Represents the range of average values (3 samples, each) of 4 commercial growing fields in Gaines County, TX. In partitioned samples, perchlorate in the whole grain (not including the chaff) measured 1300 µg/kg FW in 1 sample and was not detected in 2 samples of wheat endosperm.
[m] Study was restricted to foods outside the lower Colorado River region. Sample locations were not presented for each food item, however, the complete list of regions sampled is CA, CO, MI, NJ, NM, NY, OH, and Quebec.
[n] Samples were collected from home gardens in Gaines County, TX, and Morris County, KS.
[o] Six of the 10 alfalfa samples were sent to FDA for confirmatory analysis by IC-MS/MS. The FDA results ranged from 121 to 382 µg/kg FW.
[p] Samples were collected from a single commercial growing field in Gaines County, TX.
[q] Samples of 11 different commercially available species were collected.
[r] Value provided is the median (not the mean).
[s] When comparing means from the studies it is important to note that the different studies likely treated non-detects differently. Some studies treated non detects as one-half the MRL and others treated non-detects as zero.

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a. *FDA Targeted Sampling.* The FDA released data on perchlorate in milk, lettuce, and bottled water in November 2004. To analyze food samples, FDA used ion chromatography (IC)-tandem mass spectrometry (MS/MS), referred to as IC–MS/MS. The quantitation limits for perchlorate in these analyses were 0.5 [mu]g/L for bottled water, 1 [mu]g/kg by fresh weight (FW) for lettuce, and 3 [mu]g/L for dairy milk. The mean concentration of perchlorate in 128 lettuce samples collected in 5 states (AZ, CA, FL, NJ, TX) was 10.3 [mu]g/kg FW (FDA, 2004), and ranged from not quantifiable (NQ) to 129 [mu]g/kg FW. The mean concentrations of perchlorate in several varieties of lettuce are reported in Table 4. The mean concentration of perchlorate in 104 dairy milk samples collected in 14 states (AZ, CA, GA, KS, LA, MD, MO, NJ, NC, PA, SC, TX, VA, WA) was 5.76 [mu]g/L (FDA, 2004), with a range from NQ to 11.3 [mu]g/L. FDA (2004) detected perchlorate in 2 of the 51 bottled water samples representing 34 distinct sources collected in 12 states (CA, CO, GA, MD, MN, MO, NC, NE, PA, SC, TX, WI) at levels of 0.56 [mu]g/L and 0.45 [mu]g/L.

b. *Other Published Studies.* Sanchez (2004) and Sanchez *et al.* (2005a) report the results of an analysis of agricultural products sampled from the lower Colorado River region of Arizona and California, the Imperial Valley of California, and the Coachella Valley of California, where irrigation water is known or suspected to contain perchlorate. The studies were partially supported by the U.S. Department of

Agriculture—Agricultural Research Service (USDA–ARS). Samples of iceberg, romaine, and leaf lettuce, carrots, onions, sweet corn, squash, melons, tomatoes, peppers, broccoli, cauliflower, cabbage, durum wheat, and alfalfa were analyzed for perchlorate using ion chromatography (IC) as the primary analytical method. For these analyses, the fresh-weight method reporting limit was not identified in most cases, but was reported to range from 20 to 50 [mu]g/kg FW, depending on the moisture content of the samples (Sanchez, 2004). Sanchez *et al.* (2005a) report that the method reporting level for iceberg lettuce was approximately 20 [mu]g/kg FW and for other types of lettuce was 25–30 [mu]g/kg FW. Perchlorate in the irrigation water ranged from 1.5 to 8.0 [mu]g/L over the period of the survey (Sanchez *et al.*, 2005a).

Sanchez *et al.* (2005a) analyzed 44 samples of iceberg lettuce heads that had been trimmed of frame and wrapper leaves, which are usually removed before the lettuce is consumed. Perchlorate was quantified in 5 of the samples (ranging from 23 to 26 [mu]g/kg FW),[23] perchlorate was not detectable in 6 samples, and the results of the remaining samples were less than the method reporting limit, which the authors defined as ''a detectable peak among duplicates and/or replicates but below a level that can be quantitated.'' Perchlorate concentrations in 10 samples of romaine and green leaf lettuce ranged from less than the method reporting limit to 81[mu]g/kg FW (Sanchez, 2004).

As shown in Table 4, Sanchez (2004) also detected perchlorate in samples of melons, tomatoes, and peppers, but at levels below the method reporting limit. Perchlorate was not detected in carrots, onions, sweet corn, squash, and durum wheat. Concentrations of perchlorate in 10 samples of alfalfa ranged from 109 to 668 [mu]g/kg FW. Six of the 10 alfalfa samples were sent to FDA for confirmatory analysis by IC–MS/MS. The FDA results were generally lower than those of the corresponding samples by Sanchez (2004), ranging from 121 to 382 [mu]g/kg FW.

Sanchez *et al.* (2006) conducted studies to evaluate the uptake and distribution of perchlorate in citrus trees and the occurrence of perchlorate in lemons, grapefruit, and oranges grown in southern California and southwestern Arizona. Five whole lemon trees irrigated with Colorado River water were harvested for destructive sampling. Sanchez *et al.* (2006) estimate that the irrigation water had an average perchlorate concentration of 6 [mu]g/L. Most of the sample analysis was conducted using IC–MS/MS, having an MRL of approximately 25 [mu]g/kg by dry weight (DW). In samples of tree trunks, roots, and branches, perchlorate was close to or below the MRL. Perchlorate was much higher in the leaves than the fruit (peel and pulp), with mean concentrations of 1,835 and 128 [mu]g/kg DW, respectively.

Citrus samples were collected during 2004–2005 from the lower Colorado River Valley, the University of Arizona Research Farm, the Coachella Valley, and Los Angeles County. All analyses of fruit pulp were conducted using IC–MS/MS with an approximate MRL of 2.5 [mu]g/kg FW. For the 86 citrus samples collected, the perchlorate concentration in the fruit pulp ranged from below detection to 37.6 [mu]g/kg FW. Mean concentrations in lemons (33 samples), grapefruit (15 samples), and oranges (28 samples) were 2.3, 3.3, and 7.4 [mu]g/kg FW, respectively.

Sanchez *et al.* (2005b) surveyed perchlorate occurrence in lettuce and other leafy vegetables produced outside the lower Colorado River region. Samples were analyzed by IC, with a minimum reporting level of approximately 20 to 40 [mu]g/kg FW, depending on the leafy vegetable type. Results of some of the more heavily sampled food items are presented in Table 4.

While not shown in Table 4, Sanchez *et al.* (2005b) performed additional analysis by partitioning the leafy vegetable samples by type of culture. Perchlorate was detected in 70 of 268 samples of conventionally-grown leafy vegetables and 72 of 170 samples of organically-grown leafy vegetables. The range of perchlorate concentrations was ND to 104 [mu]g/kg FW in conventional leafy vegetables and ND to 628 [mu]g/kg FW in organic leafy vegetables. Sanchez *et al.* (2005b) analyzed the results using regression analysis and estimated that the median perchlorate concentration in organically-grown samples was 2.2 times higher than in conventionally-grown samples. The regression analysis also suggested that variation among sampling locations was greater than variation among lettuce types.

Researchers at Texas Tech University analyzed samples of dairy and soy milk using IC and/or IC/MS analytical methods with detection limits of 1 [mu]g/L or better (Kirk *et al.*, 2005). In a study of perchlorate in dairy milk, Kirk *et al.* (2005) found mean perchlorate levels of 2.0 [mu]g/L in 47 retail dairy milk samples from 11 states (AK, AZ, CA, FL, HI, KS, ME, NH, NM, NY, PA), with a range from not detected (ND) to 11.0 [mu]g/L. A single sample of soy milk was analyzed and reported to contain 0.7 [mu]g/L perchlorate (Kirk *et al.*, 2005). An earlier study by Kirk *et al.* (2003) found perchlorate ranging from 1.7 [mu]g/L to 6.4 [mu]g/L in 7 dairy milk samples purchased in a city in Texas.

Jackson *et al.* (2005) conducted limited sampling of edible and forage vegetation in 1 Texas county and in 1 Kansas home garden. In Texas, wheat and alfalfa were sampled from commercial fields irrigated with groundwater containing perchlorate from an unknown source, and a cucumber was sampled from an irrigated home garden. In Kansas, cantaloupe, cucumber, and tomatoes were sampled from an irrigated home garden near a slurry explosives site. Researchers used IC for sample analysis but did not report fresh-weight detection limits. Perchlorate was detected in all 12 samples of winter wheat heads (whole, including the chaff) at a mean concentration of 2,000 [mu]g/kg FW but perchlorate was not detected in wheat endosperm (2 samples)[24]. The mean perchlorate concentration in 3 samples of alfalfa was 2,900 [mu]g/kg FW. A cucumber sample from a Texas home garden contained 40 [mu]g/kg FW perchlorate; a sample of irrigation water from this garden contained 20.7 [mu]g/L perchlorate. In the Kansas home garden, the cucumber sample contained 770 [mu]g/kg FW perchlorate, the cantaloupe sample contained 1,600 [mu]g/kg FW perchlorate, and 2 samples of tomato contained 42 and 220 [mu]g/kg FW perchlorate. The reported concentration of perchlorate in irrigation water for the Kansas home garden was 81 [mu]g/L. EPA notes that the perchlorate levels in irrigation water samples associated with these two home gardens were significantly higher than in the vast majority of surface and ground water samples in the US.

Aribi *et al.* (2006) developed an analytical method for perchlorate that uses ion chromatography with suppressed conductivity and electrospray ionization tandem mass

[23] Sanchez (2004) presents somewhat different results. Specifically, of the 44 samples of ''edible head'' lettuce, perchlorate was quantified in one of the samples (26 [mu]g/kg), perchlorate was not detectable in 6 samples, and the remaining sampling results were qualified as <MRL, which the author defined as ''represents a seemingly detectable peak but below a level that can be quantitated.''

[24] A wheat kernel (seed) has three major parts—the bran, the germ, and the endosperm. The majority of the wheat kernel is the endosperm, which is the portion of the kernel that is retained in refined (white) wheat flours. Whole wheat flours contain endosperm, wheat bran, and wheat germ in approximately the same proportions as in the wheat kernel. Wheat flours do not contain the chaff (husk).

spectrometry (IC–ESI–MS/MS). The method was used to measure perchlorate in samples of various food products, including fresh/canned fruits and vegetables, wine, beer, and other beverages. Most samples were purchased in grocery and liquor stores in greater Toronto, Canada, between January 2005 and February 2006. Produce samples originated from many different parts of the world and all samples contained measurable amounts of perchlorate. However, the survey was limited to only a few samples of each food. Products from California, Chile, Costa Rica, Guatemala, and Mexico had the highest levels of perchlorate. Products from Canada and China had the lowest levels of perchlorate. The highest detection was in cantaloupe from Guatemala (463.50 [mu]g/kg FW). Analysis of raw asparagus (39.900 [mu]g/kg FW) and cooked asparagus (24.345 [mu]g/kg FW) demonstrated that perchlorate can remain in food processed at a high temperature. Perchlorate concentrations in 8 samples of produce from the U.S. ranged from 0.094 [mu]g/kg FW (for blueberries) to 19.29 [mu]g/kg FW (for green grapes).

Aribi et al. (2006) analyzed 77 samples of wine and 144 samples of beer from many parts of the world. All samples contained measurable amounts of perchlorate. The wine sample with the single highest concentration of perchlorate, 50.250 [mu]g/L, was from Portugal. Overall, wine samples from Chile contained the highest concentrations of perchlorate, ranging from 5.358 to 38.88 [mu]g/L in 8 samples. Twelve samples of wine from the U.S. contained perchlorate concentrations ranging from 0.197 to 4.593 [mu]g/L. Results from analysis of beer samples varied substantially among countries, with an overall range from 0.005 [mu]g/L (Ireland) to 21.096 [mu]g/L (France). Concentrations of perchlorate in 8 beer samples from the U.S. ranged from 0.364 to 2.014 [mu]g/L.

Snyder *et al.* (2006) measured perchlorate in dietary supplements and flavor enhancing ingredients collected from various vendors in Las Vegas, NV, and Seattle, WA. Analyses were performed using LC–MS/MS with a limit of detection between 2 and 5 [mu]g/kg. Perchlorate was detected in 20 of 31 analyzed supplements, with detectable concentrations ranging from 10 to 2,420 [mu]g/kg. Based on manufacturers' recommended intake of the supplements, the resulting daily oral doses of perchlorate would range from 0.03 to 18 [mu]g/day. Twelve of the supplements tested were prenatal or children's vitamins. The highest level of perchlorate (2,420 [mu]g/kg or 0.018 mg/day at the recommended daily dose) was found in a prenatal vitamin; in the remaining prenatal and children's vitamins perchlorate did not exceed 28 [mu]g/kg. The study noted that ''vitamin and mineral supplements are typically formulated to include the Recommended Daily Allowance (RDA) of iodine, a factor that would provide protection against any possible impacts of microgram levels of perchlorate found in these supplements.'' Perchlorate was also detected at 740 [mu]g/kg in a sample of kelp granules (a flavor enhancer), which equates to 2.2 [mu]g perchlorate per serving.

Martinelango *et al.* (2006a) measured perchlorate in seaweed, which is often used as a source of iodide in food and nutritional supplements. Martinelango *et al.* (2006a) collected samples of 11 different species of seaweed growing off the coast of northeastern Maine. Perchlorate was detected in all species, with concentrations ranging from 29 to 878 [mu]g/kg DW. The iodide content in the samples was much higher, ranging from 16 to 3,134 mg/kg DW. Martinelango *et al.* (2006a) found that samples of *Laminaria* species concentrated iodide more selectively than perchlorate. Laminaria is a genus of large brown seaweeds that are commonly used in kelp tablets. Martinelango *et al.* (2006a) also analyzed 4 seaweed samples that had been washed with deionized water and found that a single wash removed 38 to 73 percent of the perchlorate and 34 to 44 percent of the iodide.

D. Occurrence Studies on Perchlorate in Human Urine, Breast Milk, and Amniotic Fluid

Recently researchers have used the results of the analysis of urine samples to estimate human exposure to perchlorate. Ingested perchlorate is not metabolized by humans and is excreted largely in the urine (Merrill *et al.*, 2005). The CDC's National Center for Environmental Health (NCEH) developed a sensitive and selective analytical method to analyze perchlorate in human urine (Valentin-Blasini *et al.*, 2005). The method uses ion chromatography coupled with electrospray ionization tandem mass spectrometry (IC/MS/MS) and achieves an MRL of 0.025 [mu]g/L in human urine. The authors report that the method is robust enough to process first-morning-void urine samples, which are samples of the first voiding of urine upon waking.

Valentin-Blasini *et al.* (2005) analyzed urine samples from 61 healthy adult donors who lived in the area of Atlanta, Georgia. The urine samples were provided anonymously, without associated donor information. Perchlorate was detected in all of the urine samples, with concentrations ranging from 0.66 to 21 [mu]g/L. The authors cited dietary exposure as a potential source of perchlorate because perchlorate was found only at low levels (0.1—0.2 [mu]g/L) in area tap water samples (Valentin-Blasini *et al.*, 2005).

Valentin-Blasini *et al.* (2005) also analyzed the urine samples for creatinine, which is a metabolic breakdown product in muscles that is eliminated from the body in urine at a predictable rate. When adjusted for urinary creatinine content, the reported range of perchlorate in the samples is 1.0 to 35 [mu]g of perchlorate per gram of creatinine. The median perchlorate concentration was 3.2 [mu]g/L (7.8 [mu]g/g creatinine). The researchers stated that only 1 sample from the Atlanta population contained perchlorate at a level slightly in excess of the amount expected to be excreted by an individual exposed to perchlorate at the reference dose of 0.0007 mg/kg/day (Valentin-Blasini *et al.*, 2005). Specifically, assuming that perchlorate is excreted uniformly in urine throughout the day, a urinary excretion level of 34 [mu]g perchlorate per gram creatinine would be associated with a daily perchlorate intake of 0.0007 mg/kg/day, for a 70 kg male that excretes creatinine at a typical rate of 1.44 grams per day (g/day). These assumptions are imprecise for individual exposure assessment but allow for spot urine perchlorate excretion to be related to the reference dose for toxicological perspective. Estimating perchlorate exposure from a single spot urine sample (as opposed to a sample collected continuously over a period of time) is imprecise due to the episodic nature of perchlorate exposure and the short half-life of perchlorate in the human body. The precision of estimated individual perchlorate exposure can be improved by more precise estimation of 24-hour creatinine excretion based on sex, height, weight, and age as described by Mage *et al.* (2004). In addition, imprecision stemming from the episodic nature of perchlorate exposure can be reduced with increased sampling.

The analytical method developed by Valentin-Blasini *et al.* (2005) was further used by Blount *et al.* (2006a) to evaluate urine samples from 27 volunteers with differing dietary habits. Blount *et al.* (2006a) collected first-morning-void urine specimens from volunteers living in the Atlanta area. The study volunteers self-assessed their consumption of milk, dairy products, and green/leafy vegetables within the 16 hours before the sample was collected.

The samples were grouped into 2 categories (''one or fewer servings'' and ''three or more servings'') based on total consumption of these selected foods. Total daily perchlorate exposure was calculated using a bodyweight of 70 kg and a creatinine excretion rate of 1.44 g/day, assuming that each first-morning void urine sample was representative of that individual's daily perchlorate exposure. Each volunteer also collected a drinking water sample from home and work. Blount *et al.* (2006a) analyzed drinking water samples with the same method used for urine analysis and estimated exposure from drinking water based on a body weight of 70 kg and daily consumption of 2 liters of water per day. The mean creatinine-adjusted urinary perchlorate level was 1.8 times higher for individuals who identified themselves as consuming three or more servings of milk, dairy products, and/or green/leafy vegetables (6.13 versus 3.45 [mu]g/g creatinine). There were no significant differences in the perchlorate levels in the drinking water samples of the 2 diet groups, which ranged from <0.05 to 0.25 [mu]g/L with a median of 0.10 [mu]g/L. Using a median drinking water level of 0.10 [mu]g/L, Blount *et al.* (2006a) estimated that the perchlorate dose from drinking water was 0.003 [mu]g/kg/day. Compared to this drinking water estimate, the total perchlorate dose estimate based on mean urinary perchlorate excretion was 24 times higher (0.071 [mu]g/kg/day) and 42 times higher (0.126 [mu]g/kg/day) for the low-consumption and high-consumption diet groups, respectively. The overall range of perchlorate found in urine was 0.94 to 17 [mu]g/g creatinine with a median of 4.2 [mu]g/g creatinine.

In the largest study of its kind, Blount *et al.* (2006c) measured perchlorate in urine samples collected from a nationally representative sample of 2,820 U.S. residents, ages 6 years and older, as part of the 2001–2002 NHANES. Blount *et al.* (2006c) detected perchlorate at concentrations greater than 0.05 [mu]g/L in all 2,820 urine samples tested, with a median concentration of 3.6 [mu]g/L (3.38 [mu]g/g creatinine) and a 95th percentile of 14 [mu]g/L (12.7 [mu]g/g creatinine). Only 0.7% of the study participants had an estimated perchlorate dose in excess of 0.0007 mg/kg/day. Women of reproductive age (15–44 years) had a median urinary perchlorate concentration of 2.9 [mu]g/L (2.97 [mu]g/g creatinine) and a 95th percentile of 13 [mu]g/L (12.1 [mu]g/g creatinine). The demographic with the highest concentration of urinary perchlorate was children (6–11 years), who had a median urinary perchlorate concentration of 5.2 [mu]g/L (5.79 [mu]g/g creatinine). Blount *et al.* (2006c) estimated a total daily perchlorate dose for each adult and found a median dose of 0.066 [mu]g/kg/day (about one tenth of the RfD) and a 95th percentile of 0.234 [mu]g/kg/day (about one third of the RfD). Eleven adults (0.7%) had estimated perchlorate exposure in excess of the RfD (0.7 [mu]g/kg/day). The highest estimated exposure was 3.78 [mu]g/kg/day. Because of daily variability in diet and perchlorate exposure, and the short residence time of perchlorate in the body, these single sample measurements may overestimate long-term average exposure for individuals at the upper end of the distribution and may underestimate the long-term average exposure for individuals at the lower end of the distribution. Daily perchlorate dose is not presented for children and adolescents due to the limited validation of formulas for these age groups (Blount *et al.*, 2006c).

Valentin-Blasini *et al.* (2005) and T[eacute]llez *et al.* (2005) analyzed urine samples of pregnant women in 3 cities in Chile and found higher median levels of urinary perchlorate in cities with higher concentrations of perchlorate in tap water. Based on an assessment of drinking water intake, the researchers determined that, in all 3 cities, there was an additional source of perchlorate for the study participants that may be explained by dietary (food) intake (T[eacute]llez *et al.*, 2005). This gap between estimated perchlorate exposure and perchlorate intake from tap water consumption ranged from 21.7 [mu]g/day to 33.8 [mu]g/day in the 3 Chilean cities (T[eacute]llez *et al.*, 2005).

Martinelango *et al.* (2006b) developed a method to measure perchlorate in human urine with a limit of detection of 0.080 [mu]g/L, and reported analytical results of 9 spot urine samples from male and female volunteers. Perchlorate was present in all samples analyzed, at concentrations ranging from 2.2 to 14.9 [mu]g/L, with a median value of 8.1 [mu]g/L.

Other studies have investigated perchlorate in human breast milk. Kirk *et al.* (2005) analyzed 36 breast milk samples from 18 states (CA, CT, FL, GA, HI, MD, ME, MI, MO, NC, NE, NJ, NM, NY, TX, VA, WA, WV) and found perchlorate concentrations in all samples ranging from 1.4 to 92.2 [mu]g/L in all samples, with a mean concentration of 10.5 [mu]g/L. T[eacute]llez *et al.* (2005) report maternal parameters for participants from the study in Chile. Breast milk samples indicated that a significant amount of perchlorate leaves the body of the nursing mother through breast milk, in addition to urine. However, the breast milk perchlorate levels were highly variable and no significant correlations could be established between breast milk perchlorate and either urine perchlorate or breast milk iodide concentrations for the individuals evaluated in these Chilean cities (T[eacute]llez *et al.*, 2005). Kirk *et al.* (2006) evaluated variations of iodide, thiocyanate and perchlorate in human milk samples. These authors suggest that if the overall intake of iodide is sufficient, it is unlikely that milk with an occasional low iodide or high perchlorate content would pose a major risk to infants. However, their limited data (evaluating only 10 women) show that the milk of some women may not supply infants with adequate iodide and they suggest that it may be important to base risk assessments for perchlorate exposure on the iodide to perchlorate ratio or the ratio of iodide to a ''selectively-weighted sum of iodide uptake inhibiting agents.''

Blount and Valentin-Blasini (2006) developed a sensitive and selective method for quantifying iodide, perchlorate, thiocyanate, and nitrate in human amniotic fluid. The analytical limit of detection for perchlorate was calculated to be 0.020 [mu]g/L. Samples of amniotic fluid at 15 to 20 weeks gestation were collected from 48 healthy women in an Eastern U.S. city for analysis. Perchlorate was found in all samples tested and exhibited a log-normal distribution. The perchlorate concentrations ranged from 0.057 to 0.71 [mu]g/L with a median value of 0.18 [mu]g/L.

E. Status of the Preliminary Regulatory Determination for Perchlorate

As stated earlier, the Agency is not making a preliminary regulatory determination for perchlorate in this notice. The Agency believes that additional information is needed on the sources of human exposure if it decides to base its determination regarding health risk reduction potential on a health reference level (HRL) derived from the RfD and the relative source contribution (RSC) for drinking water. Under this approach, the Agency would use the RfD and RSC to estimate an HRL and then use this HRL as a benchmark against which to conduct an evaluation of the occurrence data. In conducting such an assessment for the 6 non-carcinogens discussed previously in this action, EPA used a 20 percent RSC, which is the lowest and most conservative RSC used to estimate an HRL. Since the initial screening of the occurrence data against the HRL resulted in a preliminary negative determination, the Agency found that it

was not necessary to further evaluate the RSC for these contaminants. In the case of perchlorate, the Agency is not at the point of being able to make either a negative or a positive determination using this approach because it is not yet clear what an appropriate RSC for perchlorate is. If EPA were to use a default RSC of 20% for perchlorate, the resulting HRL would be 5 [mu]g/L. Approximately 3.16% of the 3,858 PWSs in the UCMR1 data set had at least one detect of perchlorate greater than or equal to 5 [mu]g/L. Given this level of occurrence at the default-derived HRL, the Agency believes a better informed RSC and HRL would be needed to use this approach to determine whether regulation of perchlorate in drinking water presents a meaningful opportunity for health risk reduction.

Table 5 shows the number of systems and population served that would exceed the HRL under various RSC scenarios and the sensitivity of this estimate to relatively small changes in the estimated RSC. For example, increasing the RSC from 20 to 30 percent would lower the estimated number of systems impacted by about a third and the estimated population served by about half. Hence, the choice of an appropriate RSC and resulting HRL could impact EPA's determination of whether regulation of perchlorate represents a meaningful opportunity for health risk reduction if it uses this approach.

EPA recognizes that system-level population estimates shown in Table 5 may be conservative because some systems have multiple entry points to the distribution system and not all entry points had a positive detection for perchlorate in the UCMR 1 survey. Hence, to derive a less conservative population estimate (last column in Table 5), EPA assumed that the population for each system is equally distributed over all of the entry (or sampling) points and estimated a population-served value based on entry points that had at least 1 analytical detection for perchlorate at levels greater than each of the HRL thresholds.

TABLE 5.—UCMR 1 OCCURRENCE AND POPULATION ESTIMATES FOR PERCHLORATE AT VARIOUS HRL THRESHOLDS [a]

RSC scenarios (percent)	Estimated HRL thresholds based on various RSC scenarios [b]	PWSs with at least 1 detection ≤ threshold of interest	PWS entry or sample points with at least 1 detection ≤ threshold of interest [c]	Population served by PWSs with at least 1 detection ≤ threshold of interest [d]	Population estimate for entry or sample points having at least 1 detection ≤ threshold of interest [e]
20	5 [mu]g/L	3.16% (122 of 3,858)	1.88% (281 of 14,984)	14.6 M	4.0 M
30	7 [mu]g/L	2.13% (82 of 3,858)	1.14% (171 of 14,984)	7.2 M	2.2 M
40	10 [mu]g/L	1.35% (52 of 3,858)	0.65% (97 of 14,984)	5.0 M	1.5 M
50	12 [mu]g/L	1.09% (42 of 3,858)	0.42% (63 of 14,984)	3.6 M	1.2 M
60	15 [mu]g/L	0.80% (31 of 3,858)	0.29% (44 of 14,984)	2.0 M	0.9 M
70	17 [mu]g/L	0.70% (27 of 3,858)	0.24% (36 of 14,984)	1.9 M	0.8 M
80	20 [mu]g/L	0.49% (19 of 3,858)	0.16% (24 of 14,984)	1.5 M	0.7 M
100	25 [mu]g/L	0.36% (14 of 3,858)	0.12% (18 of 14,984)	1.0 M	0.4 M

Footnotes:

[a] These data represent summary statistics for the 3,858 public water systems that have sampled for perchlorate as a part of the UCMR 1 survey.

[b] HRL threshold = [(RfD of 0.0007 mg/kg/day x 70 kg BW for pregnant female) / (2 L DWI)] x the RSC scenario. Each HRL threshold value is converted from mg/L to [mu]g/L units and then rounded to the nearest whole number.

[c] The entry/sample-point-level population served estimate is based on the system entry/sample points that had at least 1analytical detection for perchlorate greater than the HRL threshold of interest. The UCMR 1 small system survey was designed to be representative of the nation's small systems, not necessarily to be representative of small system entry points.

[d] The system-level population served estimate is based on the systems that had at least 1analytical detection for perchlorate greater than the HRL threshold of interest.

[e] Because the population served by each entry/sample point is not known, EPA assumed that the total population served by a particular system is equally distributed across all entry/sample points. To derive the entry/sample point-level population estimate, EPA summed the population values for the entry/sample points that had at least 1 analytical detection greater than the threshold of interest.

Table 5 also includes information on the effects of using an RSC of 100% (that is, using an HRL set at the DWEL of 24.5 [mu]g/L, rounded to a whole number). Crawford-Brown *et al.* (2006), in an estimate of risk variability from perchlorate exposure through community water systems, noted that the subjects in the original 2002 Greer *et al.*, study (on which the RfD of .0007 mg/L was based) presumably had other sources of perchlorate exposure outside of the study and suggested that it may be appropriate to view their results as reflecting the effects of incremental exposure to perchlorate above the background levels already in food and water rather than the effects of total exposure, as is implicitly assumed when the HRL is derived using an RSC to account for other sources of exposure. Use of an RSC to derive the HRL is clearly appropriate when the RfD or cancer slope factor is derived from animal studies with carefully controlled exposure. Crawford-Brown *et al.* suggest, however, that an RSC is not necessary for perchlorate because there is no reason to assume that the background exposure of the study subjects was different than that of the general population. EPA notes that the sample size in the Greer study was small and EPA is not aware of data on their background exposure to perchlorate or how representative it may be. EPA requests comment on whether information is available on the background exposure of subjects in the Greer study and whether it should consider the background exposure of these subjects in determining an HRL for perchlorate.

While several States have recommended guidelines or public health goals for perchlorate, EPA recognizes that at least 1 state, Massachusetts,[25] has already promulgated a final drinking water standard for perchlorate, that other States may set drinking water standards in the future, and that these standards

[25] Massachusetts promulgated a final drinking water standard of 2 [mu]g/L for perchlorate on July 28, 2006. For more information about the final standard, see *http://www.mass.gov/dep/public/press/pchl0706.htm* (MA DEP, 2006).

could impact national occurrence estimates once these standards are fully implemented.

F. What Are the Potential Options for Characterizing Perchlorate Exposure and Proceeding With the Preliminary Regulatory Determination for Perchlorate?

While the Agency recognizes that food and other pathways may be important sources of perchlorate exposure, the Agency believes the currently available food data (summarized in section V.C.3) are inadequate to develop a better informed RSC (and HRL). First, some of the existing data are limited in their sample numbers, geographic coverage, and analytical method adequacy. Second, the current studies provide little or no data for several food groups (*e.g.*, meat, poultry, fish, eggs, root and tuber vegetables, brassica vegetables, bulb vegetables, tree fruits, legumes, and cereal grains) that account for about half of the diet (by mass) for females of reproductive age (mid-teens to mid-forties).

This section presents and requests comment on data EPA might use to estimate an RSC based on food-borne exposure as well as on several other options that the Agency is considering to better characterize perchlorate exposure and assist the Agency in making its regulatory determination for perchlorate. These options could serve as a supplement or an alternative to developing an HRL based on a better informed RSC derived from food concentration and consumption data. The Agency specifically seeks comment on the use of urine biomonitoring data in estimating perchlorate exposure. If the Agency decides to use any of the approaches discussed in V.F.2, EPA will need to determine what statistics (*e.g.*, mean, median, percentile, etc.) are most appropriate for consideration in a regulatory determination. The Agency will also conduct a peer review, as appropriate, of any new methodology it decides to use.

The Agency also invites the public to submit relevant data that may further characterize exposure to perchlorate through consumption of foods and/or through other pathways. The Agency will consider any new, relevant information/data provided in response to this action as the Agency determines whether to regulate perchlorate with a national primary drinking water regulation.

1. Use of Food Concentration and Consumption Data to Estimate an RSC. In the past, the Agency has relied on dietary exposure information from the FDA Total Diet Study (TDS) to determine the RSC allowed for drinking water and to set health goals (*i.e.*, Maximum Contaminant Level Goals) for several inorganic compounds (*e.g.*, antimony, cadmium, chromium, and selenium). Under the TDS, foods are sampled at retail outlets, prepared as they would be consumed, and analyzed for a variety of analytes (*e.g.*, nutrients, pesticides, industrial chemicals). Approximately 280 foods, covering a broad spectrum of the diet, are currently sampled in each sampling event. Sampling events (known as ''market baskets'') occur about 4 times per year, with each event being confined to 1 of the 4 regions of the country. The dietary intake of the analyzed compounds can be calculated for the U.S. population by multiplying the concentrations found in TDS foods by the consumption amounts for each food. FDA compiles food consumption amounts for the total U.S. population by gender and by age group.[26]

FDA is including perchlorate as an analyte in the 2006 TDS. EPA believes that a comprehensive dietary intake estimate for perchlorate will be useful in evaluating dietary exposure relative to drinking water. When sufficient quantitative exposure data are available (such as the data published by FDA in conjunction with the TDS), EPA can use the procedure used previously for several regulated inorganic compounds (*i.e.*, chromium and selenium) to calculate the relative source contribution for perchlorate. In these cases where dietary intake values were available, EPA subtracted the dietary intake value from the Drinking Water Equivalent Level DWEL and used the remainder as the allowance for water. This procedure assures that total exposure does not exceed the RfD.

The Agency invites the public to submit relevant data that may further characterize exposure to perchlorate through consumption of foods and/or through other pathways. This information may help the Agency in the evaluation of currently available food data and the 2006 TDS.

2. Use of Urinary Biomonitoring Data to Evaluate Exposure to Perchlorate. Researchers at CDC's National Center for Environmental Health (NCEH) have conducted a large national study of total perchlorate exposure through analysis of urine samples collected for NHANES 2001–2002 (Blount *et al.*, 2006b and 2006c). The use of urinary perchlorate excretion to estimate perchlorate exposure has been demonstrated in Valentin-Blasini *et al.* (2005), Tollez *et al.* (2005), and Blount *et al.* (2006c). While this would be the first time the Agency has used biomonitoring data to assist EPA in making a preliminary regulatory determination for a CCL contaminant, the Agency believes that estimating perchlorate exposure among large populations using urinary perchlorate excretion data may be appropriate for the following reasons:

<bullet≤ Perchlorate is not metabolized in the body and is excreted unchanged primarily via the renal pathway (Merrill *et al.*, 2005),

<bullet≤ Perchlorate does not bioaccumulate, that is, it is excreted essentially completely (Merrill *et al.*, 2005),

<bullet≤ Perchlorate has a short half-life in the human body (approximately 8 hours), simplifying the estimation of daily exposure (Greer *et al.*, 2002), and

<bullet≤ A methodology exists that allows estimation of daily perchlorate intake from all sources (*e.g.*, water, food) using standard creatinine adjustment factors to account for variations in urine concentration (Mage *et al.*, 2004).

The Agency could use the 2001–2002 NHANES urine data in several ways as described in the following paragraphs. The Agency welcomes comment from the public on these approaches, as well as suggestions for other analyses that may inform the preliminary regulatory determination for perchlorate.

One potential approach is to use the 2001–2002 NHANES urine data to directly determine whether regulation of perchlorate in drinking water presents a meaningful opportunity for health risk reduction. More specifically, we could use the urine data (as in Blount *et al.*, 2006b and c) to evaluate whether total exposure from food and water is likely to result in an appreciable risk of adverse health effects for the U.S. population. If the Agency concluded that total exposure, as estimated from the urine data, does not pose an appreciable risk, even at the upper end of the exposure distribution, then it would follow logically that reducing this exposure by regulating drinking water would not present a meaningful opportunity for health risk reduction. As summarized above, Blount *et al.* (2006c) estimated a median total daily perchlorate dose for adults of 0.066 [mu]g/kg/day (about one tenth of the RfD) and a 95th percentile dose of 0.234 [mu]g/kg/day (about one third of the RfD). Only eleven adults (0.7%) had an estimated dose in excess of the RfD (0.7 [mu]g/kg/day). EPA requests comment on whether or not these data provide an adequate basis to support a regulatory

[26] Information about FDA's TDS design, food list, analytes, and analytical results can be found at *http://www.cfsan.fda.gov/comm/tds-toc.html.* (FDA, 2006)

determination for perchlorate. EPA also requests comment on the relevance, if any, to a regulatory determination for perchlorate, of the Blount et al (2006b) study, which showed an association between T4/TSH levels in women and urinary perchlorate concentrations at levels below the RfD (see Section V.B).

EPA could also use the 2001–2002 NHANES urine data to qualitatively evaluate the importance of the water contribution to overall exposure. For this approach, the Agency could merge data from the 2001–2002 NHANES and UCMR 1 and compare the total perchlorate exposure values (based on the urine data) for the population of individuals whose drinking water contains perchlorate at various concentration levels, ranging from non-detect to the upper end of the occurrence distribution. The intent of this analysis would be to permit the Agency to determine whether total perchlorate exposure (as measured in urine) is meaningfully correlated with concentrations in local public drinking water supplies, though EPA would only use these results qualitatively because it is not possible to match up individual urine samples with individual drinking water exposures. However, the results could be useful in determining at least qualitatively the potential significance of drinking water exposure for total exposure. If there were not a significant correlation between public water system perchlorate occurrence and individual exposure as measured through biomonitoring, this might suggest that there is not a meaningful opportunity for health risk reduction through regulation of drinking water.

The Agency could also potentially use the 2001–2002 NHANES urine data to derive an RSC to use for drinking water. This could potentially be done in several different ways as follows.

a. *Use of Urinary Biomonitoring Total Exposure Value to Estimate an RSC.* One possible approach to estimating an RSC for water would be to use the urine data to estimate total perchlorate exposure, then subtract this exposure value from the reference dose and allow the remainder as the exposure limit for water. The allowed remainder divided by the RfD would be the RSC for drinking water. This approach would yield a conservative RSC value because the exposure used to represent food would actually correspond to both food and drinking water exposure, whereas, if it were possible to estimate the exposure from food alone, the relative amount allowed for water would be larger (resulting in a higher RSC and higher health reference value). As discussed in Section V.D, Blount *et al.* (2006c) estimated a total daily perchlorate dose for adults from urine data and found a median dose of 0.066 [mu]g/kg/day (about one tenth of the RfD) and a 95th percentile of 0.234 [mu]g/kg/day (about one third of the RfD). If EPA were to use the estimated 95th percentile total dose from the Blount study as if it represented the exposure from food alone, this would suggest a residual screening-level RSC of about 70% allocated to water. One possible limitation of this approach is that the Blount study estimates exposure for adults only. Therefore, an RSC developed based upon this data would not necessarily be representative of children. EPA requests comment on using this approach as the basis for deriving a screening-level RSC.

b. *Use of the Urine Data and UCMR 1 to Deduce Exposure from Other Sources and Derive the RSC.* Alternately, for those NHANES survey subjects served by public drinking water systems with positive detections for perchlorate (based on UCMR 1), EPA could estimate the expected perchlorate dose contributed by drinking water (using individual water consumption data from the NHANES survey combined with UCMR 1 data for the area in which they live) and subtract it from the total perchlorate dose (based on urinary perchlorate excretion data) to calculate the amount contributed by food. Subtraction of this calculated food contribution from the RfD would yield the amount allowed for drinking water, which could be divided by the RfD to calculate an RSC. One limitation of this methodology would be the assumption that subjects in the NHANES study are uniformly consuming drinking water that contains perchlorate at the concentration indicated in the UCMR 1 data for their area.

c. *Use of Urinary Biomonitoring Data from Exclusive Bottled Water Drinkers to Estimate an RSC.* The 2001–2002 NHANES data includes urinary perchlorate data for populations who exclusively drink bottled water. As noted in section V.C.3.a, FDA (2004) tested 51 samples of bottled water from 34 distinct sources in 12 states and detected perchlorate in 2 samples (at levels of 0.56 [mu]g/L and 0.45 [mu]g/L). These levels are well below the MRL for the UCMR 1 data and would not contribute significant amounts of perchlorate relative to the RfD. If the population of exclusive bottled water drinkers is sufficiently representative of the U.S. population, these data potentially could be used to estimate the contribution of perchlorate exposure coming from food and allow the Agency to estimate an RSC for drinking water. The RSC value could be derived by subtracting the estimated perchlorate exposure for exclusive bottled water drinkers from the RfD of 0.0007 mg/kg/day, using the remainder as the allowance for drinking water. One limitation of this methodology is that the perchlorate concentration of the bottled water used by this NHANES population is not known. Hence, we would have to assume that the bottled water concentration data collected by FDA (2004) is representative of the perchlorate concentration in the bottled water used by the NHANES exclusive bottled water population. Another limitation of this approach is that it would not subtract out the fraction of the drinking water intake that comes from water used for cooking purposes (since bottled water is probably not used by most subjects in cooking and household food preparation). It would thus produce a conservative (health protective) estimate of the RSC as it would overestimate the fraction of total exposure coming from food.

G. Next Steps

After the Agency evaluates and thoroughly reviews public comments and any new information/data on perchlorate obtained following this notice, and performs the necessary analyses, the Agency intends to move expeditiously to publish a preliminary regulatory determination for perchlorate. Depending on how quickly the Agency is able to complete the necessary analyses and determine the best approach for making this determination, EPA may be able to publish the preliminary determination in time to include a final determination for perchlorate as part of the final CCL 2 regulatory determination, which is due by July, 2008. If not, the Agency will publish its final determination for perchlorate as soon thereafter as possible. EPA does not intend to wait until the CCL 3 regulatory determination cycle to complete its determination for perchlorate.

VI. What About the Remaining CCL 2 Contaminants?

As previously stated, EPA is only making regulatory determinations on CCL 2 contaminants that have sufficient information to support a regulatory determination at this time. Section V discusses the status of EPA's review of perchlorate. For the 30 remaining chemicals and the 9 microbial pathogens, the Agency lacks adequate information in the areas of health effects or occurrence or both.

The Agency continues to conduct research and/or to collect information

on the remaining CCL 2 contaminants to fill identified data gaps. Stakeholders may be concerned that regulatory determinations for such contaminants should not necessarily wait until the end of the next regulatory determination cycle. In this regard, it is important to recognize that the Agency is not precluded from conducting research, monitoring, developing guidance or health advisories, and/or making a determination prior to the end of the next cycle. In addition, the Agency is not precluded from regulating a contaminant at any time when it is necessary to address an urgent threat to public health, including any contaminant not listed on the CCL.

Because the focus of this action is to announce and solicit public comment on the Agency's preliminary determinations for 11 of the 51 CCL 2 contaminants, this action primarily provides information on these 11 contaminants. The Agency recognizes that the public may have a particular interest in metolachlor, methyl tertiary butyl ether (MTBE), and the microbial contaminants. Therefore, this action includes some additional information for these contaminants in the following sections and requests public comment on any further data, information and/or analyses that the Agency should be aware of.

A. Metolachlor

1. Background. Metolachlor is a broad spectrum herbicide used for general weed control in many agricultural food and feed crops (primarily corn, soybeans and sorghum), on lawns and turf, ornamental plants, trees, shrubs and vines, rights of way, fencerows and hedgerows, and in forestry. Metolachlor appears to be moderately persistent to persistent and depending on the type of soil, can be highly mobile. Degradation of metolachlor in the environment is dependent on microbially-mediated and abiotic processes. Metolachlor has at least 5 major degradates. Two of the more common degradates are metolachlor ethane sulfonic acid (ESA) and metolachlor oxanilic acid (OA).

2. Health. The Agency established an RfD for metolachlor of 0.1 mg/kg/day based on an NOAEL of 9.7 mg/kg/day and a UF of 100 (USEPA, 1995). The Agency derived the NOAEL from a one-year chronic feeding study in beagle dogs where the critical effect was decreased body weight gain. Metolachlor shows some evidence of causing developmental toxicity effects in rats but none in rabbits. The doses associated with the developmental effect in rats are greater than the NOAEL and therefore the NOAEL would be protective against developmental toxicity.

Metolachlor has been evaluated for carcinogenic activity in both rats and mice. No treatment-related cancer effects were observed in 2 studies using mice. In studies using rats, metolachlor caused a significant increase in liver nodules and carcinomas in high dose females. Negative results from mutagenicity studies suggest that tumors may result from a nonmutagenic mode of action. In 1991, a peer review committee recommended that metolachlor be classified as a possible human carcinogen based on increases in liver tumors in the female rat. However, a peer review conducted in July 1994 recommended that the evidence for cancer was suggestive and should not be quantified. This recommendation was supported by negative mutagenicity data and recent metabolism data indicating that the formation of the metabolite presumed to be the ultimate carcinogen is very low (USEPA, 1995).

3. Occurrence. EPA included metolachlor as an analyte in the UCM Round 2 survey. EPA evaluated the UCM Round 2 Cross Section data and found that metolachlor was detected at or above the reporting limit of 0.1 [mu]g/L in 0.83% of the 12,953 systems that sampled for metolachlor (USEPA, 2006a).

The USGS NAWQA program included metolachlor as an analyte in its 1992–2001 monitoring survey of ambient surface and ground waters across the United States. EPA evaluated the results of the provisional data, which are available on the Web at *http://ca.water.usgs.gov/pnsp/* (Martin *et al.*, 2003; Kolpin and Martin, 2003). While the USGS detected metolachlor in both surface and ground waters, 95 percent of the samples from the various land use settings were less than 1.38 [mu]g/L. The maximum surface water concentration is 77.6 [mu]g/L (agricultural setting) and the maximum estimated ground water concentration is 32.8 [mu]g/L (agricultural setting).

4. Consideration of the ESA and OA degradates. While EPA has health and occurrence information for metolachlor itself, the Agency believes it is prudent to also consider the occurrence and exposure of the ESA and OA degradates as well. At this time, there is no finished water occurrence and exposure information for these 2 degradates from a nationally representative sample of PWSs. However, a few small-scale studies indicate that the ESA and the OA degradates may be occurring at greater frequencies and at higher concentrations than the metolachlor parent (Phillips *et al.*, 1999a and 1999b; Rheineck and Postle, 2000). In order to gather more information about the occurrence of the ESA and OA degradates in finished water (along with the metolachlor parent), the Agency has added these degradates and their parent to the second unregulated contaminant monitoring regulation (UCMR 2; 70 FR 49093; USEPA, 2005g). While EPA awaits the results of the UCMR 2 survey, the Agency is planning to update the health advisory for metolachlor to include the ESA and OA degradates. The Agency requests comment from the public as to whether updating the health advisory to include these degradates will be useful for States and public water utilities.

In addition, the Agency requests answers to the following questions and any available data:

<bullet≤ Are States collecting data on the co-occurrence of metolachlor and its degradates in source waters on a state-wide basis? In drinking water on a state-wide basis?

<bullet≤ If available, are States willing to provide data on the co-occurrence of metolachlor and its ESA and OA degradates in community and public water systems? What analytical method and reporting limit were used to gather these data?

<bullet≤ Do States have any information on the number of PWSs impacted by metolachlor and/or its degradates?

<bullet≤ Have States seen an increase or decrease in the number of PWSs impacted by metolachlor and/or its degradates?

<bullet≤ How many systems have taken wells or sources offline due to impacts from metolachlor and/or its degradates?

B. Methyl tertiary-butyl ether

1. Background

Methyl tertiary-butyl ether (MTBE) is a volatile organic compound synthesized for use as a gasoline additive. First used as an octane enhancer to improve engine performance, MTBE is also used to reduce emissions that form carbon monoxide and ozone. Leaking underground storage tanks, gasoline distribution facilities, and even recreational boating can release MTBE into the environment.

In 1997, EPA issued a drinking water advisory of 20 to 40 [mu]g/L based on taste and odor (USEPA, 1997b). EPA is currently revising its health risk assessment for MTBE, and thus, will not be making a regulatory determination for MTBE as part of this action. The IRIS Chemical Assessment Tracking System *http://cfpub.epa.gov/iristrac/index.cfm* has the most up-to-date information on

the status of the MTBF health risk assessment and interested members of the public should check that Web site to find out the latest schedule.

The Agency collected data on MTBE occurrence as part of the UCMR 1 survey. In addition, EPA evaluated several sources of supplemental occurrence information described in the supporting documentation for this action entitled ''Regulatory Determinations Support Document for Selected Contaminants from the Second Drinking Water Contaminant Candidate List (CCL 2)'' (USEPA, 2006a). Section VI.B.2 provides a summary of some of the data and information on MTBE occurrence collected to date.

2. Occurrence Information

a. *UCMR 1.* EPA collected sampling results for MTBE from over 98.9 percent (3,068 of 3,100) of the large PWSs and over 99.5 percent (796 of 800) of the small systems required to sample under UCMR 1. Based on these data, 19 public water systems (0.49 percent of the 3,864 sampled) in 14 states (CA, CT, GA, IL, MA, MO, NH, NJ, NM, NY, PA, SD, TN, and WV) reported MTBE occurrence in drinking water. These 19 systems reported MTBE in 26 samples at the minimum reporting level of 5 [mu]g/L or above, representing approximately 0.33 percent (or 754 thousand of 226 million) of the population served by the public water systems that sampled for MTBE. (USEPA, 2006a)

Of the PWSs reporting detections at or above 5 [mu]g/L (the MRL), 15 were ground water systems and 4 were surface water systems. One small ground water system (49 [mu]g/L) and 3 large ground water PWSs (48 [mu]g/L, 36 [mu]g/L, and 33.2 [mu]g/L) reported MTBE at levels greater than 20 [mu]g/L (the lower end of the taste and odor threshold). One large surface water system (33 [mu]g/L) reported MTBE at levels greater than 20 [mu]g/L. The remaining 14 systems had detects between 5 [mu]g/L and 20 [mu]g/L (USEPA, 2006a).

b. *USGS studies/surveys/reviews.* In 2003, the USGS reported results of national source water sampling (previously introduced in section III.B.2.a.(2)). USGS sampling included a random study of a representative sample of untreated source waters (known as the ''Random Survey'') and a study of source waters from areas known or suspected of having MTBE (known as the ''Focused Survey''). In the Random Survey, USGS found that none of the source waters exceeded 20 [mu]g/L, and the three highest concentration sources ranged from 6 [mu]g/L to 19.5 [mu]g/L (Grady, 2003). Of the areas known or suspected of having MTBE in the Focused Survey, USGS found that 5 percent (e.g., ground waters for 7 of the 134 systems) had concentrations greater than 20 [mu]g/L (Delzer and Ivahnenko, 2003a).

USGS also reviewed the literature for national, regional, and State MTBE information (Delzer and Ivahnenko, 2003b), including 13 state-wide assessments. This information is summarized in Table 6. USGS noted that because study objectives varied, information varied in terms of reporting levels, sampling frequencies, and sources (e.g., ambient water, public and homeowner wells, treated drinking water).

Previously, USGS (Grady and Casey, 2001) studied MTBE occurrence in the drinking water of 12 States (New England and the Mid-Atlantic). The study found less than 1 percent of the CWSs had drinking water samples at or above 20 [mu]g/L, while 7.8 percent of the CWSs had MTBE at 1 [mu]g/L or higher.

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Table 6. Summary of MTBE State-wide Assessments (Delzer and Ivahnenko, 2003b)

State Survey Summary	Reporting Limit (RL)	Detection Frequency	Median Detected Concentration	Maximum Detected Concentration
Alabama: 2000 survey of 575 PWSs. Sampling at 1,053 sources (87 surface water sources, 27 springs, 939 wells)	0.5 - 2.0 µg/L	wells: 0.53% springs: 0% surface water sources: 0%	wells: NA springs: NA surface water sources: NA	wells: 8.4 µg/L springs: NA surface water sources: NA
California: partial survey of PWS source waters, covering 105 of 245 surface water sources (3,000 samples) and 2,988 of 13,919 PWS wells in 1996-1997; supplemented by information from DHS database (50,748 samples collected between 1989 and 2001)	NA DHS database: NA	surface water sources: 46.7% wells: 1.2% DHS database: 1.1%	surface water sources: NA wells: NA DHS database: 3.6 µg/L	surface water sources: >14 µg/L (26%) wells: NA DHS database: 610 µg/L
Connecticut: 1999 annual report on organics testing at PWSs (total number of PWSs not reported)	0.5 - 2.0 µg/L	NA (detected in 57 sources waters in 40 towns)	2.7 µg/L	110 µg/L
Florida: 8,739 samples collected from 1,692 public water supplies since early 1990s.	NA	4.9% of samples, 1.2% of PWSs (89% of the detects were from 2 PWSs)	1.4 µg/L	166 µg/L
Illinois: monitoring since 1994 at approximately 80% of the State's 1,200 CWSs, most of which (92%) utilize ground water	0.5 - 1.0 µg/L	2.7% of active systems, plus 3 systems that abandoned wells following MTBE contamination	NA	NA
Iowa: 530 samples collected from 235 PWS wells in "vulnerable bedrock regions" in 1999; plus sampling of water supplies in several cities since the 1990s	Bedrock project: 15 µg/L cities: NA	bedrock project: 8 sample detections < 15 µg/L cities: NA	bedrock project: < 15 µg/L cities: NA	bedrock project: < 15 µg/L cities: 63 µg/L in Alvord's water supply before well abandoned
Kansas: 27,935 samples from 1,122 PWS wells, collected 1996 - 2000	NA	1.6% of wells	NA	1,250 µg/L
Maine: survey of 793 of 830 public water supplies and 951 private household water supplies in 1998	0.1 µg/L	public supplies: 15.8% (6% had concentrations ~ 1-35 µg/L) private supplies: 15.8%; (6.6% had concentrations ~1-35 µg/L)	public supplies: NA private supplies: NA	public supplies: < 35 µg/L private supplies: > 35 µg/L (1.1% of supplies)
Maryland: 1,084 PWSs surveyed since 1995; data also collected on private wells contaminated by LUSTs	0.5 µg/L	PWSs: 7.8% private wells: NA	PWSs: NA private wells: NA	PWSs: >20 µg/L (11 systems) private wells: NA
Michigan: 31,557 samples from 18,046 CWS, NCWS, and private wells from 1987 through 1999	1.0 µg/L	2.9% of samples and 3.0% of wells	NA	>240 µg/L (29 samples)
Missouri: MO has monitored MTBE in 1,685 PWSs since 1994	5 µg/L	0.1% of monitored PWSs statewide (2 PWSs)	NA	NA
New Jersey: samples from about 400 CWSs from 1997 to 1998; plus a random sampling of 104 domestic wells	PWSs: 0.5 µg/L private wells: 0.1 µg/L	PWSs: 14.8% private wells: 35.6%	PWSs: NA private wells: 0.48 µg/L	PWSs: 8.4 µg/L private wells: 30.2 µg/L
Wisconsin: 2,271 wells (mostly private) sampled since 1990	12 µg/L	4.4% of wells (96 private wells and 3 public wells)	NA	1,700 µg/L (private well)

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c. *New England Interstate Water Pollution Control Commission (NEIWPCC).* In 2003, the NEIWPCC surveyed the States under a grant from EPA's Office of Underground Storage Tanks (UST). Twenty-six States estimated that they had public wells that were contaminated by MTBE at some level, and of those, 5 States (ME,

NH, NJ, DE, and MD) estimated having detectable levels of MTBE in at least 100 public water supply wells. Thirteen States did not know the answer, 8 States did not respond, and 3 States reported that no PWS wells were impacted. The survey established no reporting level to define ''contamination.'' Only 3 States documented the basis for their estimates (projected from several studies, raw and treated water analyses, and a survey of funded petroleum spill projects) (NEIWPCC, 2003).

d. *California Department of Health Services.* In 2000, California developed a drinking water standard of 13 [mu]g/L for MTBE (CA DHS, 2000). According to California's annual compliance reports, there were no violations of the 13 [mu]g/L standard by public water systems in 2002 and 2003, and 2 violations at 2 public water systems (serving almost 14,000 people) in 2004 (CA DHS, 2002; CA DHS, 2003; CA DHS, 2004).

e. *Other Sources of Data.* In April 2005, the Environmental Working Group (EWG, 2005) released a report, Like Oil and Water, on their Web page. In response to Freedom of Information Act requests, 29 State agencies submitted data to EWG. EPA informally evaluated the data posted by EWG to determine if this information might be useful in projecting state-wide occurrence. While EPA found the report interesting, the data as reported on the Web lacked some of the information needed to assess the representativeness and the quality of the data. For example, States submitted different time periods of monitoring data (*e.g.*, Alaska submitted 7 months of data for 1 system during the 2000 timeframe and Illinois submitted data that spanned 1990 to 2002). States did not report monitoring results for every system. Also, the data do not indicate if the samples came from source water or finished water, from ground water or surface water, the analytical method used for analysis nor the reporting level, the frequency of the sampling (*e.g.*, annual, quarterly), number of samples from each water system, number of non-detects, etc.

3. Request for Additional MTBE Occurrence Information

As discussed earlier, EPA is not making a regulatory determination for MTBE; however, EPA is presenting this information because of ongoing interest in MTBE. And as noted earlier, additional information is presented in the regulatory support document for this action (*i.e.*, USEPA, 2006a). While the Agency waits for the final health risk assessment, EPA will continue to collect and evaluate occurrence information. The Agency requests any data, information, or analyses that may be available on the following topics:

<bullet≤ Are there additional occurrence data for MTBE in community and non-community public water systems on a state-wide or more local basis? As noted in the previous section, the State data submitted to EWG lack some elements needed to assess the quality of the data, as required in EPA's guidance for information quality guidelines (USEPA, 2003c), and project state-wide occurrence.

<bullet≤ What analytical method and reporting limit were used to gather these data?

<bullet≤ Has there been an increase or decrease in the number of impacted PWSs? Over what time frame?

<bullet≤ For those PWSs whose water supplies have been impacted, has there been an increase or a decrease in the concentration of MTBE?

<bullet≤ How many systems have taken wells or sources offline, consolidated with other PWSs, or added customers due to impacts from MTBE?

<bullet≤ What treatments are being used in the field? What range of treatment effectiveness is being achieved?

<bullet≤ Is the listing of State bans for MTBE shown in Table 7 complete? Have state-wide bans decreased MTBE contamination in drinking water?

TABLE 7.—STATE ACTIONS BANNING MTBE (STATE-WIDE)

[Adapted from USEPA, 2004g and McCarthy and Tiemann, 2005]

State	Effective date	Extent of MTBE ban
Arizona	January 1, 2005	0.3% max volume in gasoline.
California	December 31, 2003	complete ban in gasoline.
Colorado	April 30, 2002	complete ban in gasoline.
Connecticut	January 1, 2004	complete ban in gasoline.
Illinois	July 24, 2004	0.5% max volume in gasoline.
Indiana	July 24, 2004	0.5% max volume in gasoline.
Iowa	July 1, 2000	0.5% max volume in gasoline.
Kansas	July 1, 2004	0.5% max volume in gasoline.
Kentucky	January 1, 2006	0.5% max volume in gasoline.
Maine	January 1, 2007	0.5% max volume in gasoline.
Michigan	June 1, 2003	complete ban in gasoline.
Minnesota	July 2, 2005	complete ban in gasoline. (following partial ban in 2000).
Missouri	July 1, 2005	0.5% max volume in gasoline.
Montana	January 1, 2006	no more than trace amounts in gasoline.
Nebraska	July 13, 2000	1% max volume in gasoline.
New Hampshire	January 1, 2007	0.5% max volume in gasoline.
New Jersey	January 1, 2009	0.5% max volume in gasoline.
New York	January 1, 2004	complete ban in gasoline.
North Carolina	January 1, 2008	0.5% max volume in gasoline.
Ohio	July 1, 2005	0.5% max volume in gasoline.
Rhode Island	June 1, 2007	0.5% max volume in gasoline.
South Dakota	July 1, 2001	0.5% max volume in gasoline.
Vermont	January 1, 2007	0.5% max volume in gasoline.
Washington	January 1, 2004	0.6% max volume in gasoline.
Wisconsin	August 1, 2004	0.5% max volume in gasoline.

C. Microbial Contaminants

1. Evaluation of Microbial Contaminants for Regulatory Determination. The 9 microbial contaminants listed on CCL 2 include:

<bullet≤ Four virus groups—Caliciviruses, Echoviruses, Coxsackieviruses, and Adenoviruses

<bullet≤ Four bacteria/bacterial groups-*Aeromonas hydrophila; Helicobacter pylori; Mycobacterium avium intercellulare (or MAC);* and Cyanobacteria (called blue-green algae[27]), fresh water algae, and the associated toxins

<bullet≤ One group of protozoa—Microsporidia (*Enterocytozoon bieneusi* and *Septata intestinalis,* now renamed *Encephalitozoon intestinalis*).

In addition to considering if the Agency had sufficient information to address the three statutory criteria listed in section II.B.1 (i.e., adverse health effects, known/likely occurrence, and meaningful opportunity for health risk reduction), the Agency also considered whether sufficient information was available to determine whether current treatment requirements adequately controlled for any of the 9 microbial contaminants. After consideration of these factors, the Agency determined that none of the 9 microbial contaminants have sufficient information at this time to address the three statutory criteria to make a regulatory determination. Table 8 identifies the specific areas for which information is insufficient.

TABLE 8.—INFORMATION GAPS FOR THE MICROBIAL CONTAMINANTS

Health effects	Treatment	Analytical methods	Occurrence
Microsporidia	*Aeromonas*	*Aeromonas*	*Aeromonas.*
Some Cyanotoxins	*MAC*	*MAC*	*MAC.*
	Adenoviruses	*Helicobacter*	*Helicobacter.*
	Caliciviruses	Microsporidia	Adenoviruses.
	Coxsackieviruses	Some Cyanotoxins	Caliciviruses.
	Echoviruses		Coxsackieviruses.
	Microsporidia		Echoviruses.
	Some Cyanotoxins		Microsporidia.
	Helicobacter		Some Cyanotoxins.

2. Research and Other Ongoing Activities. EPA has supported an active research program to fill the information gaps on the CCL 2 microorganisms. While several examples of the ongoing research activities are listed below, further information on these and other projects can be found on EPA's Drinking Water Research Information Network (DRINK). DRINK is a publicly-accessible, Web-based system that tracks over 1,000 ongoing research projects and can be accessed at: *http://www.epa.gov/safewater/drink/intro.html.*

a. *Virus.* For the CCL virus groups (or surrogates), the Agency has initiated treatment studies that simulate realistic conditions where viruses may be protected in aggregates. EPA also plans to conduct virus removal/inactivation studies in drinking water treatment plants and/or pilot plants. In order to assess the effectiveness of treatment and to perform monitoring studies, methods development for viruses is also in progress.

b. *Bacteria.* For Aeromonas spp., EPA recently completed a one-year UCMR 1 survey of 293 public water systems. The Agency is currently attempting to characterize and distinguish pathogenic from non-pathogenic strains, as well as develop methods to detect Aeromonas virulence factors. For *H. pylori,* the Agency is in the process of developing a culture method and method for its identification. For *MAC,* preliminary drinking water surveys have been conducted using a culture method followed by genetic detection. EPA is also conducting further research into methods development and the characterization of virulence factors for this organism.

EPA has funded projects to evaluate the effect of disinfectants on cyanotoxins, and on the removal of algal cells and cyanotoxins in a pilot scale treatment plant. EPA is developing analytical methods for potential use for future monitoring and has available analytical chemistry standards for the toxins of most concern in the United States—microcystin, cylindrospermopsin, and anatoxin-a. EPA has conducted several small-scale preliminary occurrence surveys for cyanotoxins using a screening method followed by confirmation by instrumental analysis. A number of health effects studies are also in progress on several high priority cyanotoxins. These include behavioral studies in mice, acute and subacute effects in neonatal mice, and biomarkers of human exposure. Risk assessments are being conducted at EPA on the cyanotoxins to determine reference doses where possible. The Agency has organized and participated in several workshops on cyanotoxins to assess the state-of-the-science.

As an interim measure to assist public water utilities, the Agency is planning to develop an information sheet that discusses pertinent information on cyanobacteria and some of its key toxins. The document will discuss the state of the knowledge on the prevention and treatment of cyanobacteria and its toxins, as well as the available information on the potential health effects of some of the toxins. EPA requests comment from the public as to whether such a document would be useful for public water utilities.

c. *Protozoa.* EPA has several ongoing projects to evaluate the susceptibility of microsporidia to chlorine and chloramine disinfectants. EPA has sponsored methods-related projects for microsporidia, which have included the use of fluorescent gene probes, real-time PCR, concentration methods, and immunomagnetic separation. Ongoing monitoring at EPA has revealed that microsporidia are present in ground water. EPA has funded work to determine exposure to microsporidia, and to determine strains (animal and human) of Enterocytozoon bieneusi found in water. EPA also held a workshop in 2003 on microsporidia to assess the state-of-the-science.

VII. EPA's Next Steps

EPA intends to respond to the public comments it receives on the 11

[27] Cyanobacteria are called blue-green algae even though they are technically bacteria.

preliminary determinations and subsequently issue its final regulatory determinations. Although the preliminary determinations for all 11 contaminants are not to regulate, if after consideration of public comments, the Agency determines that a national primary drinking water regulation is warranted for any of these 11 contaminants, the regulation would then need to be formally proposed within 24 months of the determination and promulgated 18 months following the proposal.[28]

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Dated: April 12, 2007.

Stephen L. Johnson,

Administrator.

[FR Doc. E7–7539 Filed 4–30–07; 8:45 am]

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Federal Register

Tuesday,
May 1, 2007

Part IV

Environmental Protection Agency

40 CFR Parts 51, 52, 70, and 71

Prevention of Significant Deterioration, Nonattainment New Source Review, and Title V: Treatment of Certain Ethanol Production Facilities Under the "Major Emitting Facility" Definition; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 51, 52, 70, and 71

[EPA–HQ–OAR–2006–0089; FRL–8301–4]

RIN–2060–AN77

Prevention of Significant Deterioration, Nonattainment New Source Review, and Title V: Treatment of Certain Ethanol Production Facilities Under the ''Major Emitting Facility'' Definition

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This final rule finalizes proposed changes made to the definition of ''major emitting facility'' in the Prevention of Significant Deterioration (PSD), Nonattainment New Source Review (NSR) and Title V regulations. Two of the regulatory changes proposed addressed the major source threshold for PSD sources. The remaining proposed regulatory changes finalized in this action address when fugitive emissions are counted for purposes of determining whether a source is a major source under the PSD, nonattainment NSR or Title V programs. The proposal solicited comment on whether wet and dry corn milling facilities that produce ethanol for fuel should continue to be considered a part of the chemical process plants source category, and whether other types of facilities that produce ethanol fuel should be considered for exclusion from the definition of chemical process plants. Based on comments received and evaluated, we have included additional changes to this final rule that exclude other facilities that produce ethanol by natural fermentation and are classified in North American Industry Classification System (NAICS) code 325193 or 312140 from the definition of ''chemical process plants.''

DATES: This final rule is effective on July 2, 2007.

ADDRESSES: *Docket.* The EPA has established a docket for this action under Docket ID No. [EPA–HQ–OAR–2006–0089]. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *e.g.*, Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *http://www.regulations.gov* or in hard copy at the Air and Radiation Docket and Information Center, EPA/DC, EPA West Building, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The Air and Radiation Docket and Information Center telephone number is (202) 566–1742. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The Public Reading Room is located in the EPA Headquarters Library, Room Number 3334 in the EPA West Building, located at 1301 Constitution Ave., NW., Washington, DC. The telephone number for the Public Reading Room is (202) 566–1744. Visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor materials will be processed through an X-ray machine as well. Visitors will be provided a badge that must be visible at all times.

FOR FURTHER INFORMATION CONTACT: Ms. Joanna Swanson, Air Quality Policy Division, (C339–03), Environmental Protection Agency, Research Triangle Park, NC 27711, telephone number: (919) 541–5282; fax number: (919) 541–5509, e-mail address: *swanson.joanna@epa.gov.*

SUPPLEMENTARY INFORMATION: The title of this final rule has been changed from the proposed rule title to better reflect the final rule. The proposed rule was entitled ''Prevention of Significant Deterioration, Nonattainment New Source Review, and Title V: Treatment of Corn Milling Facilities Under the ''Major Emitting Facility'' Definition.''

The information presented in this preamble is organized as follows:

I. General Information
  A. Does this action apply to me?
  B. Where can I obtain additional information?
II. Background
III. Summary of the Final Rule
IV. Policy Rationale for Action
V. Significant Comments Received on the Proposal
  A. What comments did we receive on our proposed changes to the ''major emitting facility'' definition?
  B. Why are ethanol production facilities regulated differently under different programs and standards?
  C. Do we need to make an express section 302(j) finding?
  D. What are the enforcement implications of these final amendments?
  E. Are there any environmental and health concerns associated with this final rule?
  F. Will there be a Federal ethanol-specific VOC emissions test protocol?
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VI. Effective Date of This Rule and Requirements for State or Tribal Implementation Plans and Title V
VII. Statutory and Executive Order Reviews
  A. Executive Order 12866—Regulatory Planning and Review
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  E. Executive Order 13132—Federalism
  F. Executive Order 13175—Consultation and Coordination with Indian Tribal Governments
  G. Executive Order 13045—Protection of Children from Environmental Health Risks and Safety Risks
  H. Executive Order 13211—Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution or Use
  I. National Technology Transfer and Advancement Act
  J. Executive Order 12898—Federal Actions to Address Environmental Justice in Minority Populations and Low-income Populations
  K. Congressional Review Act
VIII. Judicial Review

I. General Information

A. Does this action apply to me?

Entities affected by this final rule are facilities that produce ethanol by a natural fermentation process that are classified under NAICS codes 325193 and 312140; and State/local/Tribal governments. Categories and entities potentially affected by this action are expected to include:

Industry group	SIC [a]	NAICS [b]
Wet Corn Milling	2046	311221
Industrial Organic Chemicals (Ethyl Alcohol)	2869	325193
Sugar Cane Mills	2061	311311
Sugar Beet Manufacturing	2063	311313
Distilleries	2085	312140
State/local/Tribal government	9511	924110

[a] Standard Industrial Classification.
[b] North American Industry Classification System.

B. Where can I obtain additional information?

In addition to being available in the docket, an electronic copy of this preamble and final amendments will also be available on the World Wide Web. Following signature by the EPA Administrator, a copy of this notice will be posted on the EPA's NSR Web site, under Regulations & Standards, at *http://www.epa.gov/nsr.*

II. Background

These regulatory changes affect the applicability provisions of two separate permitting programs: the major NSR

program and the title V programs. The NSR program legislated by Congress in parts C and D of Title I of the Clean Air Act (CAA) is a preconstruction review and permitting program applicable to major stationary sources (major sources) that construct or undertake major modifications. In areas not meeting health-based national ambient air quality standards (NAAQS) and in ozone transport regions (OTR), the program is implemented under the requirements of part D of title I of the CAA for ''nonattainment'' NSR. We call this program the major nonattainment NSR program. In areas meeting NAAQS (''attainment'' areas) or for which there is insufficient information to determine whether they meet the NAAQS (''unclassifiable'' areas), the NSR requirements for the PSD of air quality under part C of title I of the CAA apply. We call this program the Prevention of Significant Deterioration (PSD) program. Collectively, we refer to both programs as the major NSR program. The NSR regulations are contained in 40 CFR 51.165, 51.166, 52.21, 52.24, and appendix S of part 51.

Title V of the CAA required EPA to promulgate regulations governing the establishment of operating permit programs. The current regulations are codified at 40 CFR parts 70 and 71.

The CAA, as implemented by our regulations, defines the applicability of these different programs based, in part, on whether a stationary source is ''major.'' For purposes of implementing the PSD program, Congress defined the term ''major emitting facility'' in section 169(l) of the CAA. This definition contains a specific list of source categories for which an individual source will be considered a major source if it has the potential to emit 100 tons per year (tpy) of any pollutant for which the local area is in attainment with the NAAQS. This is referred to as the 100 tpy threshold. For any source not otherwise listed, a 250 tpy threshold applies. For purposes of implementing the nonattainment major NSR program, we do not apply different applicability thresholds based on the type of source category. All sources are subject to a 100 tpy threshold or less depending on the severity of the nonattainment problem.

All major sources, as the term is defined for title V purposes, are required to obtain title V operating permits. Sources required to obtain title V permits include those sources subject to PSD and nonattainment NSR. Therefore, title V relies in part on the definition of ''major emitting facility'' for the PSD program.

In addition to the determining which applicability threshold applies to a given source, the determination of whether a source is ''major'' is also partly dependent on whether the stationary source must count both fugitive and stack emissions in determining whether it exceeds the threshold. Section 302(j) provides that

> (j) Except as otherwise expressly provided, the terms ''major stationary source'' and ''major emitting facility'' mean any stationary facility or source of air pollutants which directly emits, or has the potential to emit, one hundred tons per year or more of any air pollutant (including any major emitting facility or source of fugitive emission of any pollutant, as determined by rule by the Administrator).

In 1980, we established a list of source categories that must consider fugitive emissions in source applicability determinations. We used the section 169(1) list of categories in developing our 302(j) list of categories.

This final rule involves changes to the ''major stationary source'' and ''major source'' definitions in the NSR and title V programs as this definition relates specifically to the manufacturing of ethanol through natural fermentation processes. These changes affect both the applicability threshold and whether this industry must count fugitive emissions in determining its major source status.

On March 9, 2006 (71 FR 12240), we proposed to reinterpret the component term ''chemical process plants'' within the statutory definition of ''major emitting facility'' in section 169(1) of the CAA to exclude wet and dry corn milling facilities which produce ethanol fuel (Option 1). We requested comment on another option in which we would continue to include wet and dry corn milling facilities that produce ethanol fuel within the definition of ''chemical process plants.'' (Option 2). We also proposed similarly to reinterpret the regulatory term ''chemical process plants'' on the list of source categories for which fugitive emissions must be included in determining whether the source is a ''major stationary source.''

To implement these proposed changes, we proposed to revise the definition of ''major stationary source'' under 40 CFR parts 51 and 52, and the definition of ''major source'' under 40 CFR parts 70 and 71. (See 71 FR 12240, March 9, 2006). Finally, we also requested information on other types of ethanol production facilities and comment on whether other types of facilities including those that produce potable ethanol or ethanol fuel should be considered for exclusion from the ''chemical process plants'' definitions.

III. Summary of the Final Rule

This rule finalizes Option 1 and reinterpret the component term ''chemical process plants'' within the statutory definition of ''major emitting facility'' and regulatory definitions of ''major stationary source'' and ''major source'' to exclude wet and dry corn milling facilities that produce ethanol for fuel or ethanol for food. Moreover, based on comments we received, we are extending the exclusion to all facilities that produce ethanol through a natural fermentation process that involves the use of such things as corn, sugar beets, sugar cane or cellulosic biomass as a feedstock regardless of whether the ethanol is produced for human consumption, fuel or for an industrial purpose. This includes denatured alcohol, nonpotable ethanol, nonpotable grain alcohol, potable ethyl alcohol and grain alcohol beverages. We are also reinterpreting the term ''chemical process plants'' on the list of source categories that must count fugitives emissions in determining whether a source is a major source to be consistent with the way we now interpret that term for purposes of determining the major source threshold.

As proposed, we are changing the PSD and nonattainment NSR regulations that we are amending with this action to include amendments to 40 CFR 51.165, 51.166, 52.21, and appendix S. We are also amending the 40 CFR parts 70 and 71 title V regulations. We are not making changes to 52.24 as proposed because we revised that section. Paragraph (f) now cross-references the provisions of 40 CFR 51.165 for definitions of terms under 40 CFR 52.24, and paragraph (h) no longer lists source categories.

These final rule amendments define ''chemical process plants'' under the regulatory definition of ''major emitting facility'' to exclude ethanol manufacturing facilities that produce ethanol by natural fermentation processes. In addition, we have changed our approach to defining the sources within the exclusion as explained below. As explained in the preamble to the proposed rule (71 FR at 12243), in 1981, when we originally interpreted the ''chemical process plants'' term by guidance, we did so in reference to SIC 28. Since the time we defined the chemical process plant based solely on reference to SIC 28, the Federal Government replaced the SIC code manual with the NAICS. Under the NAICS, as compared to the SIC system, there are over 350 more industries classified. Federal Government agencies have adopted the NAICS to collect

statistics from industry establishments more relevant to this economy. The NAICS gives special attention to emerging industries (such as ethanol production) and similar production processes are grouped together. The SIC system, which was last revised in 1987 does not include many of the industries included in the NAICS.

Ethanol fuel and industrial ethanol fall within NAICS 325193 (Ethyl Alcohol Manufacturing) which includes denatured alcohol, nonpotable ethanol, and nonpotable grain alcohol. The NAICS 312140 (Distilleries) includes potable ethyl alcohol and grain alcohol beverages. Even though NAICS 325193 (ethyl alcohol manufacturing) has been classified under NAICS' Chemical Manufacturing subsector, unlike under the SIC classification of 2869 (Industrial Organic Chemicals, Not Elsewhere Classified), ethyl alcohol manufacturing is within its own narrowly defined category.

The Agency has considered whether, and in what way, we might transition from use of the SIC to the NAICS for purposes of determining the scope of a stationary source in general and for other purposes such as source category determinations. We have not reached any universal conclusions. Notably, however, some commenters expressed concern that by refining the ''chemical process plants'' definition such that we no longer rely solely on SIC code 28, we would be embroiling the Agency in the ''fine grain'' analysis we sought to avoid under our initial guidance, negating the objectivity of the current approach. In view of this comment, we think it useful to consider the NAICS codes as a potential tool to address the commenters' concerns. At proposal, we did not use SIC codes to define the facilities that are subject to these changes. We have decided to use NAICS codes to define these facilities in the final rule because the narrow classification of the NAICS codes for ethyl alcohol manufacturing (NAICS code 325193) and distilleries (NAICS code 312140) under the NAICS is useful and eliminates the problem of having to do a ''fine grain'' analysis.

Accordingly, in response to commenters, our final rule references the NAICS codes 325193 and 312140 to exclude facilities using a natural fermentation process to produce ethanol from the definition of ''chemical process plants.'' We believe that by defining the ''chemical process plants'' in this way, we retain the objectivity and ease of implementation inherent in our original guidance.

The remaining regulatory changes address when fugitive emissions are counted for purposes of determining whether a source is a major source under the PSD, nonattainment NSR, or title V programs. Our final rule treats the term ''chemical process plants'' in those regulations in the same manner as we treat it for purposes of determining the major source threshold.

IV. Policy Rationale for Action

In our proposed rule, we expressed several reasons to support our proposal to change the definition of ''chemical process plants.'' First, we cited concerns related to the disparate treatment of ethanol fuel production verses production of ethanol intended for human consumption by applying two different major source thresholds. Because the two manufacturing processes are substantially similar, we believed that the process should be treated identically for purposes of the PSD and title V regulations regardless of the intended product. We also cited concerns that continuing to regulate the ethanol fuel industry, under the 100 tpy major source threshold, regardless of the production method could stymie the growth of the industry, and hamper our nation's efforts toward energy independence. Some commenters agreed with our general approach. Other commenters asserted that a mere similarity in processes did not justify our proposed redefinition of the ''chemical process plant'' category. Other commenters questioned whether permitting agencies treated the two types of ethanol production differently for regulatory purposes.

After reviewing the comments, we re-examined whether our policy concerns remain valid, and affirm our conclusion that a change in the ''chemical process plant'' category definition is warranted. Although we received conflicting information as to how permitting authorities regulate ethanol intended for human consumption, especially at plants that also produce ethanol for fuel, we maintain the fundamental premise for our proposal, that ethanol, regardless of intended use, is produced through substantially similar processes, and that similar processes should be regulated in a similar way. Although there may be jurisdictional differences in the way these industries are regulated, we believe this further supports the need to clarify the definition of ''chemical process plants'' relative to the ethanol production industry as a whole and does not negate the fundamental basis on which we proposed the rule.

We continue to believe that supporting our nation's efforts toward energy independence is an important national goal, and that this consideration is appropriate in deciding how to balance our nations economic growth with environmental protection. The Energy Policy Act of 2005 (Pub. L. 109–58) established a renewable fuel standard (RFS) that requires an increasing use of renewable fuels in our nation. It is clear that continued growth of the ethanol industry will play a vital role in achieving our nation's energy and environmental objectives.

While we are uncertain what impact this regulatory action may have on furthering our progress toward the goal of energy independence, we believe that including ethanol fuel in the ''chemical process plants'' presented potential obstacles for growth in the industry. These obstacles primarily include the time it takes to obtain a preconstruction permit, and, in some cases, the potential costs that may be incurred as a result of having to apply additional emissions controls. As we discuss, in section V, we conclude that this rule is not likely to result in significant net environmental harm. Nonetheless, even if our consideration of potential environmental consequences understates potential negative environmental consequences, we believe that the potential for other environmental benefits and the desire to support our nation's energy policy objectives outweigh any potential negative environmental consequences that could potentially result from this rule.

We maintain, as we did in the proposal preamble, that we have the discretion to define ''chemical process plants'' to exclude wet and dry corn milling facilities. As stated above, we based our proposed rule on the premise that ethanol production should be treated similarly regardless of whether it is produced using either the wet or dry corn milling process, and regardless of whether the end product is used as fuel or for human consumption because the process steps involved are essentially the same. As we noted in the proposal, the only difference is the final step where a small amount of denaturant (such as gasoline) is added to render the ethanol unfit for human consumption. This rationale also supports expansion of the exclusion to all facilities that produce ethanol through a natural fermentation process. We received numerous comments supporting this finding. Although some commenters pointed to differences in the production process, we are not persuaded that the differences justify disparate regulatory treatment. We also received comments justifying the expansion of our regulatory exclusion to other feedstock and end product uses. We discuss our

responses to these comments in more detail in section V of this preamble. We did, however, receive a few comments stating that our regulatory approach is fundamentally flawed, because regardless of the similarity of process, ethanol fuel and perhaps ethanol production in general should be regulated under the 100 tpy threshold.

Some commenters assert that we are not entitled to deference because such facilities fall within the plain meaning of the term ''chemical processing plant.'' Others assert that section 169(1) shows Congress' intent to focus on a facility's finished product and economic sector in which an industry competes.

We do not believe that the term ''chemical process plant'' is subject to a ''plain meaning interpretation.'' There is not a universally accepted definition of chemical process, and accepted definitions differ depending on whether you view the term from a purely scientific sense or from an engineering sense, or for economic purposes. The scope of the chemical industry is in part shaped by custom rather than by logic and excludes industries that nevertheless engage in chemical processes, *e.g.*, petroleum refineries are a separate category on the section 169(l) list.[1] One definition offered by the commenter is so broad it would encompass nearly every manufacturing activity regardless of source category, and would render other categories on the source category list redundant. The specific chemical process relevant here, natural fermentation, is common to many industries. For example, natural fermentation is used by non-ethanol producing food manufacturers which Congress chose not to subject to the 100 tpy. We find no ''plain meaning'' definition of ''chemical process plant'' that can be applied in light of these facts. Accordingly, we do not believe that whether or not an industry engages in a ''chemical process'' and specifically whether it engages in ''natural fermentation'' can be used as the decisive factor in determining whether Congress intended the industry to be included within the ''chemical process plants'' category.

We also disagree that section 169 clearly shows Congress's intent on what factors we must consider in making source category determinations. As discussed below, we have used a variety of considerations in making source category determinations. We generally have not conducted economic analysis in making these decisions, nor have we based our decision solely on the end product produced or strictly followed an SIC approach for all categories.

V. Significant Comments Received on the Proposal

Significant comments received on, and our responses to, the proposed amendments to the ''major emitting facility'' definition are presented in the following paragraphs.

A. What comments did we receive on our proposed changes to the ''major emitting facility'' definition?

The **Federal Register** proposal preamble notes that most ethanol is produced in the U.S. from sugar or starch-based feedstock using two basic processes: The dry mill process and the wet mill process. The preamble stated that wet milling operations are specifically addressed under SIC Code 2046 (''Wet Corn Milling'') under Major Group 20 (''Food and Kindred Products''). Wet corn milling units engaged in producing food products are subject to the 250 tpy threshold under PSD. The proposal provided that (1) Both wet and dry corn milling processes can produce ethyl alcohol for human consumption, (2) the processes are identical to those which produce ethyl alcohol for fuel (with some exceptions), and (3) industry stakeholders believe that the thresholds should be the same. Based on these reasons, we proposed to redefine ''chemical process plants'' under the definition of ''major emitting facility'' found in section 169(l) of the CAA to exclude wet and dry corn milling facilities that produce ethanol for fuel (Option 1).

Several commenters on the proposal argued that there was insufficient explanation as to why we proposed the change for only one type of facility (*i.e.*, corn milling facilities). Some of these commenters provided that we should extend the proposed exclusion to cellulosic biomass, sugar beets, and/or sugar cane facilities that produce ethanol fuel. A few commenters supported equal treatment of corn milling facilities regardless of the ethanol end product (*i.e.*, for human consumption, ethanol fuel, industrial ethanol). The Corn Refiners Association (CRA) suggested that we expand the exclusion to all fermentation processes that result in products other than ethanol (in addition to ethanol) that replace petroleum feedstocks or are used to make food products (*e.g.*, citric acid made from corn, propylene glycol made from corn), however, expanding to products other than ethanol is not within the scope of this rulemaking as it was not discussed at proposal.

This final rule finalizes the exclusion for wet and dry corn milling ethanol production facilities and expands that exclusion to include ethanol production facilities that produce ethanol by natural fermentation included in NAICS codes 325193 and 312140 (includes denatured alcohol, nonpotable ethanol, nonpotable grain alcohol, potable ethyl alcohol, and grain alcohol beverages).[2]

The following subparagraphs present greater detail on the comments received on the proposed ''major emitting facility'' definition and whether the ''chemical process plants'' exclusion for corn milling ethanol fuel production facilities should be expanded to facilities that produce ethanol fuel from cellulosic biomass, sugar beets, and sugar cane; and facilities that produce industrial ethanol from corn, cellulosic biomass, sugar beets, and sugar cane.

1. Proposed Treatment of Corn Milling Facilities Under the ''Major Emitting Facility'' Definition

Comments: One commenter asserted that the EPA, when applying section 169(1), needs to discern whether a facility's primary activity is a type listed as a 100 tpy ''major'' source in section 169(1)—in this case, whether a facility's primary activity is a chemical production process. Another indicated that our established policy requires that EPA look at the primary product produced and that we have not explained our change in policy.

Response: While this rule represents a change in our definition of ''chemical process plants'', it does not represent a change in our general approach to determining the scope of source categories. In our proposed rule, we pointed to our August 7, 1980 rulemaking wherein we indicated that we would use the 2-digit ''Major Group'' listings as defined by the SIC manual of 1972 (as amended in 1977) for purposes of determining the scope of the source. In subsequent guidance, we clarified that we did not necessarily intend to follow the 1980 preamble approach for defining the scope of the source when determining the applicable major source threshold once the source is defined.[3]

[1] Chemical reaction. (2007). In *Encyclopedia Britannica*. Retrieved April 5, 2007, from Encyclopedia Britannica. Online: *http//www.britannica.com/eb/article9110109*; Chemical industry. (2007). In *Encyclopedia Britannica*. Retrieved April 5, 2007, from Encyclopedia Britannica. Online: *http//www.britannica.com/eb/article9108378*.

[2] North American Industry Classification System. United States, 2002. Expanded Edition with Added ''Bridges.'' Executive Office of the President. Office of Management and Budget. Pgs. 235–236, and pg. 313.

[3] *See e.g.* Memo. Edwin B. Erickson, Regional Administrator, to George Clemon Freeman, Counsel for Reserve Coal Proportion Company, July 06,

Continued

Importantly, contrary to some commenters' assertions, EPA explicitly rejected the use of the ''primary activity test'' as the decisive means of defining source categories listed under section 169(1). *Id.* As the proposal preamble explains, the SIC manual was not designed for regulatory application, but was developed primarily for the collection of economic statistics and for the consistent comparison of economic data between various sectors of the U.S. economy. The use of SIC codes by the EPA is not required by the CAA, nor was it referenced in any legislative history related to section 169(1) of the CAA. While it may be appropriate for economic statistical purposes to place certain types of sources in the same or in different categories, EPA never intended the SIC code to be the decisive factor for determining whether a given stationary source should be regulated as a listed source category.

As one commenter properly pointed out, we use the SIC code manual only as the starting point for determining which pollutant-emitting activities should be considered as part of the same source category, but rely on case-by-case assessments to determine whether a particular stationary source belongs in a given source category. (Docket No. EPA–OAR–HQ–2006–0089–0086).[4]

Using this case-by-case approach, we applied different rationales for determining if a particular stationary source falls in a given source category. For example, we relied on the existing NSPS definition of municipal waste combustor in determining whether a source falls within a listed category. *Id.* We have also generally stated that we believe that Congress intended that we consider the source's pollutant-emitting activity in determining whether a source is within a listed source category rather than the source's finished product. In some cases, the listed source category does not directly correspond to a specific SIC code, and we considered the type of feedstock, the process steps, and end products produced to determine whether a given stationary source was part of the source category.[5]

For the chemical process plant category, EPA took a much more straightforward approach. Instead of specifically considering the pollutant emitting activity, the feedstocks, process steps, end products, or application of existing NSPS definition to making case-by-case determinations, EPA chose to specifically define the category based on SIC 28. We based this decision on a desire to promote consistency with source scope determinations, and for ease of implementation and objectivity.[6] Notably, however, in that same memorandum we stated that we have the ability to amend the definition of chemical process plant to add to or delete from the scope of the source category, especially in light of the inconsistent treatment of the alcohol fuel and beverage alcohol processes, but declined to do so at that time. With this action, we are acting in light of that continuing discretion and the facts before us now.

Comment: Several commenters assert that EPA places too much reliance on Congress' use of the report submitted by Research Corporation of New England (''Research Corp. report'') and the fact that ethanol production was not specifically addressed in the report. Commenters assert that Congress' silence can not be taken as an intent to exclude ethanol from the ''chemical process plants'' definition. One commenter believes, that the mere fact that chemical processes occur and that toxic chemicals are added is enough to conclude that Congress would intend to regulate the industry as a chemical process plant. A commenter also stated that Congress used broad terms like ''chemical processing plants'' precisely to capture new ways of making products and to avoid having to change the statute in the future to capture these activities.

Response: As noted in the proposal preamble and repeated here, section 111 of the CAA requires the Administrator of EPA to establish Federal standards of performance for new stationary sources which may significantly contribute to air pollution and was intended by Congress to complement the other air quality management approaches authorized by the 1970 CAA. After enactment of section 111, EPA hired Research Corporation of New England (Research Corp.) to study stationary sources of air pollution in order to establish priorities for developing and promulgating NSPS.

Because of limited resources, EPA could not feasibly set NSPS requirements for all categories of stationary sources simultaneously. Therefore, the goal of the Research Corp. study was to identify sources for which NSPS controls would have the greatest impact on reducing the quantity of atmospheric emissions. Research Corp. examined approximately 190 different types of stationary sources that potentially could be determined to be major emitting facilities, and provided information on the types of air pollutants that those sources emitted. The Research Corp. study was used by EPA in setting priorities for the order in which it would promulgate NSPS requirements for categories of stationary sources.

The Research Corp. study was also relied on by Congress in identifying the 28 categories of stationary sources specifically listed in the definition of the term ''major emitting facility'' in section 169(1) of the CAA. 122 Cong. Rec. 24,520–23 (1976). As explained by Senator McClure in the Congressional Record, the EPA Administrator examined the data from the draft Research Corp. study and determined that 19 of the stationary source categories examined should initially be classified as major emitting facilities. Senator McClure further explained that the Senate Committee added nine more categories of stationary sources to the 19 selected by EPA for a total of 28 source categories. 122 Cong. Rec. at 24,521.2

As discussed in the proposal preamble, in discussing the specific sources identified in section 169(1), Senator McClure stated:

> Mr. President, I ask unanimous consent that an extract from that report of the Research Corp. of New England, listing the 190 types of sources, from which the EPA took 19, and the committee took 28, be printed in the Record at this point as an illustration of what the committee examined and the kinds of sources the committee intended to include and exclude, recognizing that it is neither exclusive nor invariable. There is administrative discretion to add to the list, to change the list. But the committee spoke very clearly on its intent on that question.

122 Cong. Rec. at 24,521 (1976).

As a result of Senator McClure's action, the table from the draft Research Corp. report containing the list of 190

1996; and Memo. *Request for PSD Applicability Determination*, Golden Aluminum Company, San Antonio, TX, from William B. Hathaway, Director Air, Toxics and Pesticides Division to Steve Spraw, Deputy Executive Director, Texas Air Control Board, July 28, 1989.

[4] See Memo. *Treatment of Aluminum Die Casting Operations for the Purposes of New Source Review Applicability*, from Thomas C. Curran, Director Information Transfer and Program Integration Division, to Director, Office of Ecosystem Protection, Region I, *et.al.*, December 4, 1998, and Memo. *Applicability of Prevention of Significant Deterioration (PSD) and New Source Performance Standards (NSPS) to the Cleveland Electric Incorporated*, Plant in Willioughby, Ohio, May 26, 1992.

[5] See Memo. *Treatment of Aluminum Die Casting Operations for the Purposes of New Source Review Applicability*, from Thomas C. Curran, Director Information Transfer and Program Integration Division, to Director, Office of Ecosystem Protection, Region I, *et. al.*, December 4, 1998.

[6] See Memo. *Classification of the Bardstown Fuel Alcohol Company under PSD*, from Edward E. Reich, Director Division of Stationary Source Enforcement, to Thomas W. Devine, Director Air and Hazardous Materials Division, Region IV, August 21, 1981.

types of sources was printed in the Congressional Record. The approximately 190 source categories identified in Research Corporation's report were further classified into ten general groups for purposes of the study—stationary combustion sources, chemical processing industries, food and agricultural industries, mineral products industries, metallurgical industries, and miscellaneous sources (evaporation losses, petroleum industry, wood products industry, and assembly plants).

For the chemical process industry grouping, the Research Corp. study considered 24 different source categories and their associated pollutants. Notably, within the chemical process industry listings in the 1977 final report and in the 1976 draft report (as incorporated into the Congressional Record) there is no listing which refers to ethanol production, ethanol fuel production, or corn milling operations.

Given this history, we agree with commenters that Congress' silence on the matter can not be taken as an intent to exclude ethanol, nor however, do we believe that the silence can be taken as an intent to include ethanol within the chemical process plant definition. It is precisely because Congress did not express an intent, and because the Congressional record shows that Congress recognized that the list was neither ''exclusive or inclusive'' that we believe we have discretion to determine whether or not the ethanol industry belongs in the chemical process plants source category.

We are not persuaded that the mere fact that chemical reactions occur or that toxic chemical are added would have compelled Congress to include the industry within the category. These factors are too broad and too common in a multitude of industries to be effective criteria for categorizing sources.

Comment: We received many comments supporting our position that basic steps of both processes are similar for both wet and dry corn milling. One commenter explained that a plant may produce beverage, industrial, and ethanol fuel at the same plant using the same equipment.

Conversely, one commenter provided that the production of ethanol for fuel involves processes that are different in character than production of ethanol for human consumption, involving more steps and additional distillation that is necessary, among other things, to produce 100% ethanol (200 proof) needed for use as a fuel. This commenter pointed out that the closer the distillation process gets to producing 100% ethanol, the more energy/fuel is consumed, the more steps required, and the more pollutants emitted from the chemical processing plant.

One commenter explained that while the two processes are theoretically the same, ethanol fuel is produced on a much larger scale, and competes with other fuel markets. They provided that alcohol for human consumption does not contain as much alcohol as ethanol fuel after the distillation process (40–50% compared to 90–100% ethanol), and is subject to different regulations (*e.g.*, health, food safety). The commenters also asserted that the use of a molecular sieve in ethanol fuel production distinguishes this production from human alcohol consumption.

Finally, one commenter asked EPA to explain in greater detail its conclusion that the two processes are the same.

One commenter stated that ethanol fuel production facilities are more like refineries than an alcohol for consumption facility. They argued that ethanol fuel production facilities should be regulated similarly to a chemical process plant as that is what they are producing.

Response: In the U.S., ethanol (ethyl alcohol) is currently being produced either synthetically or through the fermentation of sugars derived from agricultural feedstocks. For ethanol produced synthetically, either ethylene or hydrogen (H_2) and carbon monoxide (CO) are used as the feedstock. As of 2002, only two facilities in the U.S. were producing synthetic ethanol.[7] The majority of ethanol produced in the U.S. is produced from sugar or starch-based feedstock (*e.g.*, corn, millet, beverage waste) using two basic processes: the dry mill process and the wet mill process. The key difference between these two processes is the initial treatment of the grain. In the wet mill process, the grain is soaked and then ground to remove germ, fiber, and gluten from the starch prior to cooking.

In the dry mill process, the grain or feedstock is not separated into its constituent parts prior to cooking. Both wet and dry milling operations produce ethanol as well as other coproducts. ''Co-products from the dry mill process, separated from the ethanol in the distillation step, include distiller's dried grain (DDG) and solubles (S), which are often combined and referred to as DDGS. DDGS is used as an animal feed. In the wet mill process, co-products are separated from the ethanol production process in the initial grinding or milling step. Coproducts from the wet milling process include fiber and gluten, which are used for animal feed and corn oil.'' [8]

Most new ethanol production capacity comes from dry mill processing facilities. Wet milling operations, on the other hand, can produce ethanol, including ethanol for fuel, but are typically primarily engaged in producing starch, syrup, oil, sugar, and by-products, such as gluten feed and meal. For ethanol which will be used as fuel, toxic solvents (typically gasoline) are added to the ethanol to render it unfit for human consumption (denatured). This additional step is required to develop ethanol fuel regardless of whether the dry or wet mill process was employed to develop the initially potable ethanol.

We recognize that though the corn milling ethanol production processes for ethanol fuel and ethanol for human consumption are theoretically the same, ethanol fuel is produced on a much larger scale, and competes with other fuel markets. We also acknowledge that alcohol for human consumption does not typically contain as much alcohol as ethanol fuel (or some other denatured ethanol products (*e.g.*, denatured ethanol products made for industrial use) after the distillation process (40–95% for distilled spirits), and is subject to different regulations (*e.g.*, health, food safety). This does not negate the fact that the natural fermentation and distillation processes (though the number of distillation steps and length of fermentation may vary) up until the time the denaturant is added for ethanol fuel (or other denatured ethanol products) are similar. We are not persuaded that these differences are significant or that they warrant different treatment under PSD. Given that the basic goal of PSD are to ensure that economic growth will occur in harmony with the preservation of existing clean air resources, that other regulations in place ensure equivalent or near equivalent BACT level of control will continue, and that a State's minor NSR program will apply when major NSR/PSD does not apply, we believe that the basic goal of PSD will be maintained.

2. Expansion to Other Ethanol Production Processes

Comments: Supports Expansion to Other Feedstock. Two commenters requested that the proposed preferred

[7] Memorandum from Mary Lalley, Eastern Research Group, Inc., to Bob Rosensteel. Ethanol Production Industry. U.S. EPA, July 2, 2002. See Docket No. EPA–HQ–OAR–2006–0089–0009.

[8] Memorandum from Mary Lalley, Eastern Research Group, Inc., to Bob Rosensteel. Ethanol Production Industry. U.S. EPA, July 2, 2002. See Docket No. EPA–HQ–OAR–2006–0089–0009.

option (Option 1) be expanded to include facilities that produce ethanol fuel from molasses.

One commenter noted that there are facilities other than corn milling which are capable of producing ethanol, notably molasses processing plants, and they should also be excluded from the definition of ''major source'' under the PSD, NSR, and title V programs. They provided that processes for both the production of ethanol from sugarcane molasses and from corn are similar, and because the processes are similar, the air emissions from the production of either product would also be similar.

One commenter stated that EPA's proposed rulemaking specifically requested public comments with respect to how future technological developments in the ethanol industry may be affected by the proposed rulemaking. They explained that while the current ethanol industry is dominated by the wet and dry corn milling process, the future of the ethanol industry could involve additional grain feedstocks such as wheat, barely, or rice as well as cellulosic feedstock's such as wood waste, switchgrass, and municipal solid waste. This commenter provided that they believed since EPA's proposal is rather narrowly focused on wet and dry corn milling newer ethanol production technologies currently under development could fall into the same regulatory quandary EPA is trying to correct through their proposal. They recommended that EPA's final rulemaking be expanded to also cover the other ethanol production technologies that may be developed in the future. They suggested that the EPA modify the currently proposed rule language to adopt language more consistent with the various NSPS rules (such as the synthetic organic chemical manufacturing industry (SOCMI) wastewater NSPS Subpart YYY standard) and exclude any process that uses ''natural fermentation'' to produce ethanol from the definition of a ''chemical processing plant'' under section 169.

One commenter stated that they believed that it is appropriate to treat all other types of facilities which produce ethanol from cellulosic biomass feed stocks similarly to how corn milling facilities are being proposed to be treated under Option 1.

One State commenter provided that other environmental rules have made distinctions with regard to applicability between ethanol by fermentation/biological processes and synthetic ethanol production:

1. NSPS subparts NNN and RRR—excludes ethanol by fermentation. The commenter stated that EPA has previously determined that ethanol-manufacturing facilities may be exempt from NSPS subparts RRR and NNN on a case-by-case basis. The commenter explained that in this instance, the ethanol facilities in question use a biological process to ferment the converted starches in corn into ethanol. These NSPS subparts did not envision unit operations for biological processes.

2. Categorical waste water effluent limits for Organic Chemicals, Plastics and Synthetic Fibers, part 414—excludes ethanol by fermentation. The provisions of this part do not apply to any process wastewater discharges from the manufacture of organic chemical compounds solely by extraction from plant and animal raw materials or by fermentation processes.

The commenter argued that EPA's proposal of Option 1 would be consistent with the above programs and that the exclusion should not be limited to ''corn'' wet and dry milling to make ethanol fuel. They supported their position by stating that several plants currently use milo along with corn to make ethanol fuel, and that the future of ethanol appears to be in the use of biomass, *i.e.*, cellulosic material. They explained that the only difference would be that the feedstock is a biomass material other than corn; and that fermentation and distillation processes would be essentially unchanged. They asserted that if the rule is not expanded to exclude cellulosic material, there could be a negative impact on the growth of cellulosic ethanol. This commenter argued that this could have an unintended complication as the energy balance favors ethanol from cellulosic feed stock over ethanol by corn.

One commenter stated that it should not matter what biomass or carbohydrate feedstock is used in the ethanol production process as the natural fermentation and distillation steps would be the same as they are for corn milling ethanol production.

One commenter provided that chemical feed stocks made from renewable sources should all be excluded as many of the products subject to the definition of chemical process plant were originally synthetically produced when SIC codes were established (*e.g.* citric acid and propylene glycol made from corn).

Opposes Expansion to Other Feedstock

One commenter opposed any suggestion to exclude ''other types of facilities which produce ethanol fuel, such as those using cellulosic biomass feedstocks, *e.g.*, solid waste, agricultural wastes, wood, and grasses * * * from the chemical process plants definition due to having production processes similar to those found at wet and dry milling facilities in cases where potable ethanol or ethanol fuel is being produced,'' or for any other reason. They provided that while they believed that the use of ethanol (especially cellulosic ethanol) as a transportation fuel has significant potential environmental benefits, the high cost of natural gas had recently caused a shift from the use of natural gas to coal for process heat which they believed would lead to an erosion of the carbon benefits of displacing petroleum-based fuels.

Response: In the proposal preamble, we solicited comment on whether other types of facilities that produce ethanol fuel, such as those using cellulosic feedstocks, *e.g.*, solid waste, agricultural wastes, wood, and grasses, should also be considered for exclusion from the chemical process plants definition due to having similar processes to those found at wet and dry milling facilities in cases where potable ethanol or ethanol fuels is being produced. We requested information, including process flow diagrams, on the processes that would be used to develop ethanol using other feedstock. Process diagrams were provided that indicated that although the processes to produce sugars from these feedstocks differ, similar fermentation and distillation processes in the production of ethanol fuel from cellulosic material would be employed. Commenters also provided process diagrams illustrating similar processes in the production of ethanol from molasses (which is used as a feedstock in the production of rum). As with cellulosic feedstocks, the breakdown of these feedstocks to produce sugars may differ, but the ethanol fermentation and distillation processes were similar. In molasses (using both sugar beets and sugar cane feedstock) ethanol production, the molasses is diluted with water, acidified to precipitate minerals and then decanted to produce the mash. Yeast and nutrients are added to the mash and fermentation converts the sugars in the molasses to alcohol. There, fermented mash is then distilled to separate and concentrate the ethanol. The ethanol is dehydrated and, if being used to produce fuel alcohol, denatured. There are currently no U.S plant producing ethanol from sugar feedstocks (sugar beets, sugar cane) therefore there is little data available on their feasibility as an ethanol feedstock, however, Brazil and

several other countries are producing ethanol from these feedstocks.

In cellulosic ethanol production, acid is introduced to the feedstock at high temperatures to release hemicellulose sugars (depending on the type of cellulose used). If acids are toxic, they are removed prior to saccarification (break down of starches) and fermentation steps. Enzymatic hydrolysis to produce sugars from cellulose is another alternative being researched in pilot and demonstration commercial plants. The result is a ''beer'' with 4 to 5 percent alcohol content by weight. The distillation step is employed to produce ethanol at about 92 to 93 percent alcohol which must be processed by a vapor-molecular sieve (to further dehydrate the ethanol) to create fuel (the last step involving the adding of a denaturant). It is important to note that the use of a molecular sieve is not unique to cellulosic biomass ethanol production facilities as it is something that is used at many corn milling ethanol production facilities. Molecular sieves have become a popular means to dehydrate ethanol as they are low cost, environmentally friendly, and require less energy. Facilities that use molecular sieves replace azeotropic distillation systems that use cyclohexane or benzene (HAP), which were expensive, costly to operate, and energy intensive.[9] There is currently no commercial cellulosic ethanol production plant operating in the U.S., however, there are several existing pilot plants, and several commercial plants are in the planning stages.

Based on the process diagrams and information received from commenters that indicate that the fermentation and distillation processes are similar (included as part of the technical record), even though the pre-steps and after-steps may differ, we are expanding the exclusion of the definition of ''major emitting facilities'' to include ethanol production facilities that produce ethanol through natural fermentation processes included in NAICS codes 325193 or 312140.

We are not excluding other chemicals (*e.g.*, citric acid and propylene glycol made from corn) made from renewable sources with this final rule. The scope of this rule is ethanol production and processes and there was no solicitation, or sufficient basis provided, to support expansion of exclusion to other chemicals.

[9] BBI International. INNOVATIONS in Dry-Mill Ethanol Production.

B. Why are ethanol production facilities regulated differently under different programs and standards?

Several commenters provided input on the historic regulatory treatment of wet and dry corn milling facilities which produce ethanol fuel. Some of the commenters stated that EPA's proposal to exclude wet and dry corn milling facilities from the definition of ''chemical process plants'' was consistent with historic regulatory treatment, while others argued that it was inconsistent with historic regulatory treatment.

Comments: The following comments were received on the historic and current regulatory treatment of wet and dry corn milling facilities that produce ethanol fuel.

<bullet≤ One commenter requested clarification of rule applicability, with regards to ethanol production, of numerous NSPS and MACT standards.

<bullet≤ Two industry commenters suggested that the rule include changes to the relevant NSPS under 40 CFR part 60 since alcohol production facilities are potentially subject to several standards of performance for new stationary sources, including 40 CFR part 60, subparts Kb (volatile organic liquids storage vessels), VV (equipment leaks of volatile organic compounds (VOC) in the SOCMI), NNN (SOCMI distillation operations), and RRR (VOC emissions from SOCMI reactor processes.

<bullet≤ Two State commenters provided examples where wet and dry corn milling facilities which produce ethanol fuel are treated as chemical process plants (40 CFR part 60, subparts VV, NNN, RRR (in Minnesota); 40 CFR part 63, subpart FFFF Miscellaneous Organic NESHAP (the MON Rule); AP–42 (Chapter 9.9.7 for Corn Wet Milling)).

<bullet≤ Two environmental consultants, two industry commenters, and one State noted that EPA rulemakings and associated interpretive guidance have either established exemptions (or allow sources to seek exemptions on a case-by-case basis) for chemicals produced through fermentation (as with corn milling ethanol production) from various SOCMI industry regulations, including the NSPS subparts RRR (SOCMI process reactors) and YYY (SOCMI wastewater units).

<bullet≤ One State commenter stated that categorical wastewater effluent limits for Organic Chemicals, Plastics, and Synthetic Fibers found in 40 CFR part 414 (promulgated under the Clean Water Act) excludes ethanol manufacturing by fermentation.

<bullet≤ Two industry commenters were concerned that the 27th listed source category in the NSR and title V programs also regulates ethanol plants as a result of the NSPSs captured under this source category.

<bullet≤ One environmental commenter stated that EPA has treated ''ethanol blending facilities''—facilities that mix ethanol into gasoline—as refineries. 40 CFR 80.2(u). (''Ethanol blending plant means any refinery at which gasoline is produced solely through the addition of ethanol to gasoline, and at which the quality or quantity of gasoline is not altered in any other manner.'') (emphasis added). Additionally, the commenter argued that EPA has referenced the distinction between ''chemical grade'' ethanol that is used in transportation fuel and other kinds of ethanol. See 40 CFR 79.55(e)(1)–(2).

Response: The applicability of differing rules is standard-specific and determinations were made under individual rulemakings and will not be changed under this rulemaking. There is no directive for the applicability to be the same across CAA programs and standards and applicability determinations need to be determined on a case-by-case, or standard-by-standard, basis.

For example, ethanol is listed as a SOCMI chemical for which 40 CFR part 60, subpart YYY (SOCMI wastewater units) applies, however, the supplemental proposed rule (63 FR 67988; September 12, 1994) excludes certain processes from the definition of chemical process unit (CPU) because they were not considered SOCMI processes, but are sometimes associated with SOCMI processes. Organic chemicals extracted from natural sources or totally produced from biological synthesis such as pinene and beverage alcohol were specifically excluded from the CPU definition. Under 40 CFR part 60, subpart YYY, the determination for excluding biological processes was based on the designation for the process unit, in contrast to the plant site. Under the 40 CFR part 63, subpart FFFF (the Miscellaneous Organic National Emission Standards for Hazardous Air Pollutants (NESHAP) (the MON)) standards, the applicable miscellaneous organic chemical process unit for which standards apply includes all equipment that collectively function to produce a product or material described in the standard (including denatured alcohol). The pollutant to be controlled (*e.g.*, HAP, VOC, particulate matter (PM)), processes to be controlled, available control technologies, timing of standard development, and program and standard directives drive the applicability of individual standards.

As for the commenters' concern that the 27th listed source category in the NSR and title V programs regulates ethanol plants as a result of the NSPSs captured under this source category, this concern would not be valid as all of the NSPSs listed by the commenters (40 CFR part 60, subparts Kb, VV, NNN, and RRR) were proposed and promulgated after August 7, 1980. The 27th listed source category referenced by the commenters includes ''[a]ny other stationary source category which, as of August 7, 1980, is being regulated under section 111 or 112 of the CAA.''

C. Do we need to make an express section 302(j) finding?

As noted in the proposal preamble, when we promulgated the list of source categories relative to the definition of ''major emitting facility'' in the NSR regulations on August 7, 1980 (45 FR 52676), we adopted this same list to identify source categories for which fugitive emissions were to be counted in determining whether a source was a major source. We promulgated the 28 source categories as a result of the decision in *Alabama Power* v. *Costle*, 626 F. 2d. 323 (D.C. Cir. 1979). In *Alabama Power*, the court held that ''fugitive emissions are to be included in determining whether a source or modification is major only if and when EPA issues an appropriate legislative rule.'' The proposed rule Option 1 was to change the definition of chemical process plants with the definition of major stationary source and major source and would correspondingly also change our interpretation of that term relative to the 302(j) source category list. At proposal we stated that since we were not changing the list of source categories in the regulations, a section 302(j) finding was unnecessary. Some commenters on the rule disagreed with EPA's position, and stated that EPA needs to make an express section 302(j) finding in order to redefine when fugitive emissions are counted.

Comments: Several commenters opposed EPA's proposal to de-list corn-based ethanol fuel production from the list of facilities identified by EPA, pursuant to CAA section 302(j). One commenter stated that the EPA can not avoid making the necessary determinations to list a facility or source pursuant to section 302(j) by merely listing categories and later determining which sources and facilities to include in the category. The commenter asserts that, in 1980, the EPA determined that ''chemical process plants,'' as defined in the SIC Manual, which specifically includes ethanol production plants, are a type of source category for which fugitive emissions should be counted. The commenter stated that EPA made this determination, based on its finding that these sources could degrade air quality significantly, and that the costs of listing this category were not unreasonable compared to the benefits. The commenter provided that the CAA does not allow EPA to identify generic categories that include unspecified sources. The commenter argued that EPA's proposal violates the CAA and EPA's own prior interpretation of the CAA.

Another commenter stated that the EPA must specifically evaluate whether eliminating this requirement is appropriate based on criteria that relate to the intent of the PSD program and the air quality impact of such emissions. The commenter explained that the EPA has adopted criteria for the very purpose of determining whether to consider fugitive emissions—those criteria require EPA to examine (1) Whether sources in the category could degrade air quality; and (2) whether the cost of controlling fugitives are unreasonable compared to the expected benefits. The commenter argued that it would be arbitrary and irrational for EPA to affirmatively change its treatment of these sources without subjecting that decision to a meaningful substantive evaluation. The commenter asserts that because the initial classification imputed a need to address fugitive emissions from these plants, and because nothing in EPA's proposal functions to counter that expectation, the commenter believes that it was not rational for EPA to exclude ethanol fuel plants from the fugitive emissions requirements without conducting an appropriate assessment.

Response: As we stated in the proposal, we are not changing the list of categories that we developed by rule under section 302(j). We are merely reinterpreting what is included within the definition of one of those categories. When EPA added chemical processing plants to the section 302(j) list in 1980, it did so based on a very general finding that sources within the category could degrade air quality and did not make any specific determination as to the appropriateness of counting fugitive emissions from any particular source types that may fall within the category. Thus, we do not think that interpreting the category to exclude a narrow set of facilities triggers the section 302(j) rulemaking requirement that applies when categories are added to the list.

Nonetheless, even if this action triggers the section 302(j) rulemaking requirement, we believe this rulemaking constitutes a sufficient section 302(j) rule that is consistent with the way we interpreted that requirement in 1980 and re-affirmed in 1984. (45 FR 52676, 52690 (Aug. 7, 1980) and 49 FR 43202 (Oct. 28, 1984)). Specifically, we determined that our action to list a category under section 302(j) may be based on a policy decision after considering certain criteria, that we do not need extensive technical analysis to support our determination, and that the purpose of rulemaking is to afford the public an opportunity to comment on the Administrator's decision.

In 1979, when we initially proposed to use the section 169(1) source category list, our stated rationale for the proposal was only that we decided to focus first on the listed sources because of our experience in quantifying the ''fugitive emissions'' from these sources. (44 FR 51924, 51931 (Sept. 5, 1979)). Similar to comments received on this proposed rule, we received comments then that our rulemaking then was inadequate, and that we should have conducted technical analysis to support our proposed rule. We rejected commenters assertions. We also stated that the purpose of the rulemaking was to afford the public the opportunity to comment on the Administrator's decision, and to allow commenters to present factual or policy arguments that it would not be appropriate to include fugitive emissions in threshold calculations. *Id.* In our 1980 final rule, we stated that our decision to use the section 169(1) source category list was ''a matter of policy.'' We reiterated our position that we had greater experience in quantifying fugitive emissions from sources on the section 169(1) source category list; and, we observed that those sources have traditionally been considered the major polluters in the country. Despite the limited nature of the technical support for our proposal, we concluded that we conducted an adequate section 302(j) rulemaking since the affected sources were afforded an opportunity to comment on our policy decision. (45 FR at 52690–92).

In 1984, after re-examining our interpretation of the section 302(j) requirements, we affirmed that the rulemaking requirements of section 302(j) were intended to afford the public an opportunity to comment on the Administrator's decision to list a category, and that we were not required to undertake extensive technical analysis to support our determination. That 1984 preamble discussion addressed two criteria relevant to the Administrator's decision to require sources to include fugitive emissions in threshold applicability determinations. We note that commenters

mischaracterized the manner in which the two criteria operate. The final rule stated that

> [a] determination by EPA that the sources in a category pose a threat of significant air quality degradation in effect establishes a presumption that the sources should be subject to PSD and nonattainment review * * *. Commenters then may seek to rebut this presumption by producing a record that unreasonable social or economic costs relative to the anticipated benefits would occur if PSD or nonattainment review were applied to a particular category of sources * * *

(49 FR at 43203–08).

Importantly, we discussed these criteria in light of our overall belief that listing a category involved the Agency's exercise of policy discretion for which we carry a very low analytical burden in deciding to list a source category. Under this interpretation, section 302(j) functions as a useful ''safety valve,'' while at the same time minimizing the expenditure of Agency resources. 49 FR 43202, 43208 (October 26, 1984). Notably, the 1984 final rule preamble did not address how or whether that requirement applies to EPA's decision to interpret a category already on the list to exclude a narrow set of sources.

Consistent with the ''safety valve'' purpose served by a section 302(j) rulemaking, we believe that it is not necessary to require a negative finding with respect to the same criteria before we interpret a category on the list to exclude certain types of sources. In sum, having made a policy decision based on a limited technical finding, we do not believe that our technical burden now in acting to refine a category on the list, should be greater than the technical analyzes we undertook in listing the categories in the first instance.

Notably, as we stated, when EPA added ''chemical processing plants'' to the section 302(j) list in 1980, it did so based on a very general finding that sources within the category could were considered major polluters. We did not make any specific determination as to the appropriateness of counting fugitive emissions from any particular type of stationary sources within that category. At the time we conducted the section 302(j) rulemaking, few ethanol facilities existed and inclusion of ethanol manufacturers was not specifically analyzed in our section 302(j) rule. When we examined the issue more closely in 1981, we made a policy decision without conducting technical analysis, to include ethanol fuel manufacturing within the chemical processing plant category. We based this decision on a desire to maintain consistency with use of SIC 28 and ease of implementation. Thus, before now, we considered this industry to be a source within the listed category. However, we find that the category should not include these sources or others who engage in natural fermentation process to produce ethanol. We believe that it is not necessary to require a negative finding with respect to the criteria that apply to list a category under section 302(j) before we interpret a category on the list to exclude certain types of sources. We believe that the economic and policy rational for the exclusion of certain ethanol production facilities from the chemical processing plant category for purposes of defining major emitting facility that we present elsewhere in the preamble to the proposed rule and in this preamble also provides ample support for a section 302(j) determination not to count fugitive emissions from such facilities.

This decision is precisely the kind of ''flexibility to provide industry-by-industry consideration and appropriate tailoring of coverage'' envisioned by the *Alabama Power* Court (*Alabama Power Co.* v. *Costle*, 636 F. 2d 323, 369 (D.C. Cir. 1979). Having been afforded the opportunity to comment on the Administrator's decision, commenters failed to present compelling factual or policy arguments based on specific information which show that our policy decision is inappropriate. Accordingly, we have satisfied the section 302(j) rulemaking requirement.

D. What are the enforcement implications of these final amendments?

Comments: One commenter asserted that the new rule would represent a drastic about-face in Federal environmental policy, and could trigger revoking of consent decrees, refunds of fines, and removal of pollution control equipment. The commenter explained that in the last four years, Department of Justice (DOJ) and EPA attorneys have consistently argued, in at least nineteen separate Federal court complaints, that ethanol plants, including those with product lines of both fuel and beverage ethanol, are chemical manufacturing facilities under section 169(1) of the CAA, 42 U.S.C. 7479 (1).

Specifically, this commenter indicated that the Federal government has argued in some of these complaints that ethanol production plants are facilities for synthetic organic chemical manufacturing and are affected facilities under part 60, subpart VV, 40 CFR 60.480, and are subject to the leak detection and monitoring requirements on 40 CFR 60.482–1 through 60–489, which govern the synthetic organic chemical manufacturing industry.

The commenter stated that the EPA formally charged that ethanol fuel facilities were chemical plants in 2002, when the EPA and the State of Minnesota filed complaints against all 12 Minnesota ethanol plants. Those complaints stated that the plants were major emitting sources under section 169 (1) of the CAA, 42 U.S.C. 7479 (1). Those cases were settled when these plants agreed to install thermal oxidizers and other additional pollution control equipment on their plants to bring their emissions per criteria pollutant to below 100 tpy. The companies were also fined from $18–42,000 a piece. A companion complaint was also filed, and settled, against Ace Ethanol in Wisconsin.

The commenter expressed that the DOJ stated in a December, 2005 press release that 83% of the ethanol industry is under consent decrees. The decrees were all imposed to enforce the PSD provisions of the CAA under the legal theory that the ethanol plants were synthetic organic chemical manufacturing plants. All of these consent decrees required the plants to keep their emissions of each criteria pollutant below 100 tpy. Some decrees also required compliance with the leak detection and monitoring requirements found at 40 CFR 60.482–1 through 60–489, which govern the synthetic organic chemical manufacturing industry.

In sum, the commenter stated that DOJ and EPA have consistently stated in court documents on nineteen separate occasions over the last 4 and one-half years that ethanol plants are chemical manufacturing plants. The commenter further stated that the DOJ and EPA have committed countless thousands of hours of staff and attorney time, laboring to advance this position. The commenter argued that the proposed preferred Option 1 could produce a situation where some or all of these companies, especially those who have been charged within the last several months (Cargill, MGP, Golden Triangle, AGP, and others) could claim that the consent decree terms, such as the 100 tpy limit per pollutant, no longer applies to their plants. Any plant who has not had their consent decree discharged could immediately apply to have the decree dissolved since the decrees' emissions limits no longer apply to ethanol plants. Additionally, the commenter asserts that these companies could ask the EPA to pay them back the millions in fines that they paid. The commenter is concerned that under Option 1, companies would be entitled to remove their thermal

oxidizers when their current permits expire.

One commenter representing State and local governments opposed the EPA's preferred option (Option 1). They argued that if new facilities are allowed to construct without controls options, then EPA may face future lawsuits from existing facilities, insisting on a level playing field, for removal or relaxation of their control strategies. The commenter expressed that the EPA should uphold their previous decisions to enforce installation of pollution control technologies at all ethanol facilities.

Response: This rule should have no effect on the existing consent decrees and the obligations of the sources to implement the consent decrees. The consent decrees are binding legal documents. The provisions of the consent decrees, by their terms, do not allow a source to alter its consent decree obligations as specified therein. Any civil penalties that had been due and owing to the United States have been paid into the United States Treasury. Even if the United States were so inclined, refunds of civil penalties from the United States Treasury would be unprecedented.

The conditions for termination of the consent decrees are specified expressly in each consent decree. Such consent decrees can only be terminated after the source completes its consent decree obligation and demonstrates compliance with the consent decree terms to the satisfaction of the United States. One of those terms is that a source obtains a Federally-enforceable operating permit incorporating the terms of the consent decree.

Our rationale for this final rule is explained in detail elsewhere in the preamble to the final rule. That we took actions to enforce the requirements in place before this rule does not undermine the basis for this rule. Existing facilities located in attainment areas would be required to maintain their existing permit limits and other permit requirements unless and until revised through a permitting procedure which, to be consistent with CAA section 110(a)(2)(C) and 40 CFR 51.160, must be shown not to cause or contribute to a violation of the NAAQS. We believe that raising the threshold from 100 tpy to 250 tpy in attainment areas will likely encourage facility expansions and construction of larger, more economically efficient plants, which in turn, will emit less emissions per gallon of ethanol produced. The 100 tpy threhold on the other hand encourages the construction of more numerous, less economically efficient smaller facilities. In addition, as noted below, the environmental and health impacts of this rule are limited.

E. Are there any environmental and health concerns associated with this final rule?

Several comments were received concerning the potential negative impacts to the environment based on our proposed change. Some of the significant comments and concerns are provided in the following paragraphs.

Comment: Several commenters expressed that increasing the PSD threshold for ethanol production facilities from 100 tpy to 250 tpy could lead to emissions increases that would not occur in absence of this rulemaking.

Response:

1. Introduction

We acknowledge that there may be some emissions increases as a result of this rulemaking. Over the past 25 years, domestic ethanol fuel production has steadily increased due to changing environmental regulation, Federal and State tax incentives, and market demand, including an increasing number of State ethanol mandates, the phase out of MBTE, and elevated crude oil prices. In order to meet current and future demand, new facilities may be constructed or existing facilities may need to be expanded. However, we do not expect many new facilities to be constructed (other than those already planned) in the short-term (*e.g.*, over the next 5 years). As noted later, we predict that the revision of the major source threshold applicable to the ethanol fuel industry will allow for the construction of larger, more economically efficient plants which, in turn, will emit less emissions per gallon of ethanol produced. Comments submitted on the proposal concurred with that prediction. (See Docket Nos. EPA–HQ–OAR–2006–0089–0086, 0039, 0040, 0045, 0046, 0050, 0057, 0058, 0062, 0063, 0065, 0066, 0067, 0068, 0069, 0072, 0073, 0075, 0076, 0077, 0078, 0079, 0085, 0090, 0091, 0092, 0093, 0094, 0098, 0100, 0101, 0102, 0103, 0104, 0105, 0107, 0108, 0110, 0111, 0112, 0113, 0114, 0115, 0116).

There are an estimated 114 facilities that currently exist in the U.S. that produce ethanol by natural fermentation as of March, 2007. Of these, an estimated 7 of the facilities are planning expansions. Eighty additional ethanol production facilities are currently under construction. Existing ethanol production capacity is estimated at 5,600 million gallons year (mgy). New construction and expansions will add an estimated 6,400 mgy to existing capacity. The estimated total capacity (inclusive of expansions and new constructions) will be about 12,000 mgy (12 billion gallons year (bgy)) once expansions and new constructions are completed.[10]

Commenters expressed concern that this rule would result in emissions increases because (1) The rule increases the PSD major source threshold from 100 tpy to 250 tpy for the subject ethanol production facilities (new or existing facilities) in attainment areas; and (2) that, for new sources, fugitive emissions will no longer be included in calculations to determine whether a source is a major PSD source in attainment areas or to determine nonattainment NSR applicability. Section 2 of this response section discusses our consideration of the potential for emissions increases due to the increased threshold, section 3 discusses our consideration of the potential for emissions increases due to facilities no longer needing to count fugitives when determining whether they are a major source, and section 4 presents our overall conclusions.

2. Increase in Major Source Threshold

Emissions data. One industry commenter provided estimates indicating that a controlled 110 mgy ethanol production facility could be assumed to emit 100 tpy and that a controlled 250 mgy ethanol production facility could be assumed to emit 250 tpy.[11] The commenter reported that emissions from both of these facilities are based on conservative potential to emit estimates, presenting worst-case operating scenario emissions and that actual plants generally emit less than their potential to emit estimates. As noted later, we believe future economies of scale will potentially drive the expansion and construction of facilities with capacities equal to or greater than 250 mgy with actual emissions being less than 250 tpy. Thus, under this scenario, production of ethanol would result in less emissions per gallon produced than today.

Volatile organic compounds (VOC) emissions occur from the cooling system baghouses, dryers, CO_2 fermentation scrubbers, equipment leaks, transfer, and storage vessels.

Estimates provided include estimates for emissions of nitrogen oxides that result from fuel combustion in the thermal oxidizers and dryers. The

[10] Ethanol Biorefinery Locations; U.S. Fuel Ethanol Industry Biorefineries and Production Capacity; updated March 13, 2007.

[11] ICM, Inc., Air Dispersion Modeling Study. 100 TPY vs. 250 TPY. April 28, 2006. Attachment 3. (EPA–HQ–OAR–2006–0089–0086, Attachment 3).

potential to emit estimates assume that 100% of the NO_X emissions are emitted in the form of NO_2 to depict a worst-case scenario.

Carbon monoxide (CO) emissions are also attributed to fuel combustion at the thermal oxidizers and dryers. As such, CO emissions were also included in their potential to emit estimates.

Emissions of particulate matter less than 10 microns (PM_{10}) result from grain unloading and loading, grain handling and milling, natural gas combustion and process operations such as dryers and cooling towers, as well as from truck traffic and haul roads. As noted, particulate emissions are generated by grain receiving, milling and distillers dried grains and solubles (DDGS) loading. Most of these emissions are controlled by baghouses.

Haul road emissions are generally dependent on the amount of vehicle miles traveled on the roads (more miles traveled equate to higher emissions). Grain fugitives are assumed to be controlled by a choked flow system, which reportedly is the typical control for fugitive particulate emissions.

Carbon monoxide and VOC emissions are typically the largest source of emissions from these facilities and are the likely pollutants that would trigger major PSD/NSR review.[12] Based on this, we have focused our analysis on increases in CO and/or VOC emissions that could potentially occur as a result of increased production and this rulemaking. We acknowledge that emissions increases in NO_X and PM_{10} could also occur concurrent with CO and/or VOC emissions increases, but these pollutants are not as relevant to the major source determinations for ethanol plants. Additionally, we note that since ozone generation is dependent on the mixing of VOCs and oxidized nitrogen in the presence of sunlight, control of VOCs in NO_X-limited environments may not be the best solution for reducing ground-level ozone emissions in those environments. Addressing other pollutants may result in greater environmental benefits.

Attainment areas. There are an estimated 171 denatured ethanol production facilities located or are planned to be located in attainment areas. If we assume that a 110 mgy ethanol production facility can be controlled under a 100 tpy threshold (for VOC and CO) including fugitives, it then can be assumed that facilities that have capacities less than or equal to 110 mgy are either controlled as synthetic minors or are uncontrolled facilities that have emissions that fall below the 100 tpy emissions threshold (for VOC and CO). Additionally, given that a 250 mgy ethanol production facility can be controlled under a 250 tpy threshold (for VOC and CO), including fugitives, it then can be assumed that facilities that have capacities greater than 250 mgy are currently regulated as major sources.

Several commenters have provided that there are many ethanol production facilities that take on BACT controls in order to be permitted as ''synthetic minor'' sources or are subject to controls or PTE restrictions that may be similar to BACT controls because of other existing regulations (*e.g.*, NSPSs, NESHAP, State regulations). (See Docket Nos. EPA–HQ–OAR–2006–0089–0086, 0057, 0074). We do not have sufficient information to discern the number of facilities that are synthetic minor. However, those facilities which must comply with NSPS, NESHAP or State regulations will continue to be subject to those regulations as those requirements are unaffected by this rule change. In addition, we do know that there are approximately 6 facilities located in attainment areas that have low production capacities (less than 6 mgy). The emissions from these facilities would likely fall below both a 100 tpy and 250 tpy threshold and ethanol production is likely a secondary process at the facility (*e.g.*, ESE Alcohol, Inc. in Leoti, KS has an ethanol production capacity of 1.5 mgy from seed corn; Land O' Lakes of Melrose, MN has an ethanol production capacity of 2.6 mgy from cheese whey). For the purposes of this analysis, we assume that these small production capacity facilities will not be affected by this rulemaking.

Based on this rulemaking, existing facilities located in attainment areas would be required to maintain their existing permit limits and other permit requirements unless and until revised through a permitting procedure which, to be consistent with CAA section 110(a)(2)(C) and 40 CFR 51.160, must be shown not to cause or contribute to a violation of the NAAQS. In addition, any expansion would also have to comply with any applicable NSPS, NESHAP, or State regulation.

Most of the existing ethanol production facilities in attainment areas have current production capacities less than 110 mgy and would, therefore, likely be either synthetic minor or actual minor source facilities, with a few facilities likely being permitted as major PSD sources. Given a worst-case scenario, the maximum these facilities could emit as a result of a change or modification and solely by the threshold being increased to 250 tpy is 249 tpy (up to the major source threshold).

New facilities located in attainment areas would be subject to a 250 tpy major source applicability threshold when determining major source applicability. Therefore, these new facilities would be allowed to emit up to 249 tpy (and produce up to 250 mgy) VOC and/or CO as minor sources as a result of the major source threshold being increased from 100 tpy to 250 tpy.

Although other factors may influence the construction of new ethanol production facilities in the future, we do not expect many additional facilities to be constructed over the next 5 years as a result of this rule.

Over the past 25 years, domestic ethanol fuel production has steadily increased due to changing environmental regulation, Federal and State tax incentives, and market demand, including an increasing number of State ethanol mandates, the phase out of MBTE, and elevated crude oil prices. We assume, and commenters have supported that, under a 250 tpy threshold, there is incentive to construct more efficient facilities with larger capacities. (EPA–HQ–OAR–2006–0089–0086). Therefore, in the future, economies of scale will potentially drive the expansion and construction of facilities with capacities equal to or greater than 250 mgy with actual emissions being less than 250 tpy. Thus, under this scenario, production of ethanol would result in less emissions per gallon of ethanol produced today.

Nonattainment areas. There are an estimated 23 ethanol production facilities located in or planned to be located in ozone nonattainment areas (12% of all facilities).[13] In nonattainment areas, existing ethanol production facilities will continue to be subject to the 100 tpy threshold, therefore, there will not be emissions increases as a direct result of this rulemaking associated with increasing the major source threshold in attainment areas for these existing sources.

3. Impact of Not Counting Fugitives in Emissions Applicability Calculations

Emissions data. For fugitive emissions, we used the potential to emit emissions estimates provided by a commenter when considering the potential VOC and CO fugitive

[12] ICM, Inc., Air Dispersion Modeling Study. 100 TPY vs. 250 TPY. April 28, 2006. Attachment 3. (EPA–HQ–OAR–2006–0089–0086, Attachment 3).

[13] Memorandum to Docket EPA–HQ–OAR–2006–0089. Spreadsheet Presenting Ethanol Production Facility Locations and Ozone Nonattainment Designations. April 2007.

emissions from the 110 mgy and 250 mgy model plants.[14] Based on these estimates, an estimated 16% of plant VOC and/or CO emissions from the 110 mgy production plant are fugitives, and 13% of plant VOC and CO emissions from the 250 mgy production plant are fugitives.[15]

Attainment areas. Existing facilities subject to a PSD permit will need to continue to include their fugitive emissions, as permitted, in attainment areas. This is because existing permit limits and other permit requirements remain in effect and enforceable unless and until revised through a permitting procedure which, at a minimum,[16] to be consistent with CAA section 110(a)(2)(C) and 40 CFR 51.160, must be shown not to cause or contribute to a violation of the NAAQS and to comply with all applicable requirements. When determining whether an emissions increase is significant, these sources would still be required to count their fugitives.

New facilities located in attainment areas would be subject to a 250 tpy major source applicability threshold and would no longer need to count fugitives when determining major source applicability. Therefore, these new facilities would be allowed to emit up to an additional 33 tpy (and produce up to 250 mgy) VOC and/or CO (assuming VOC and/or CO fugitives account for 13% of facility wide VOC and/or CO emissions) as minor sources as a result of this rulemaking.

As we noted previously, we do not expect many new facilities to be constructed over the next 5 years. However, provided that there is construction of more facilities over the next 5 years, such a facility would be able to emit 33 tpy more VOC and/or CO emissions (assuming 13% of 250 tpy are fugitive emissions no longer required to be included in the major source applicability calculations) than it would have prior to this rulemaking.

Nonattainment areas. As noted in the introduction, there are concerns that emissions may increase in nonattainment areas because fugitive emissions will no longer be required to be included in calculations to determine nonattainment NSR applicability. As noted previously, in nonattainment areas, both existing and new ethanol production facilities will continue to be subject to the 100 tpy threshold. Conservatively, approximately 23 of the 194 facilities (approximately 12 percent) are located in ozone nonattainment areas.[17]

Of the estimated facilities located in ozone nonattainment areas, 4 of the facilities have reported capacities below 6 mgy. These types of facilities produce ethanol from waste beverages, waste beer, and/or cheese whey and more than likely produce ethanol secondary to other processes at the facility (*e.g.*, the Golden Cheese Company of California has a reported ethanol production capacity of 5 mgy). As with the small production capacity facilities mentioned previously that are located in attainment areas, we do not believe that these facilities will be affected by this rulemaking.

Existing facilities subject to a nonattainment NSR permit will need to continue to include their fugitive emissions, as permitted, in nonattainment areas. This is because existing permit limits and other permit requirements remain in effect and enforceable unless and until revised through a permitting procedure which, to be consistent with CAA section 110(a)(2)(C) and 40 CFR 51.160, must be shown not to cause or contribute to a violation of the NAAQS and to comply with all applicable requirements. When determining whether an emissions increase is significant, these sources would still be required to count their fugitives.[18]

We believe that very few ethanol production facility constructions in nonattainment areas will occur in the near future and that future facilities (as with existing facilities) will likely be located near an applicable feedstock (such as corn). Currently, and in the near foreseeable future, corn is the primary feedstock used in ethanol production in this country and the bulk of the corn grown in this country is located in attainment areas, and transportation costs may influence decision makers to locate such plants close to the feedstock. In the future, where cellulosic materials will be used as a feedstock for ethanol production on a commercial scale, agricultural and other waste may be used. We believe that this rulemaking, which increases the PSD major source threshold to 250 tpy, will provide decision makers with additional incentives to locate these facilities in attainment areas.

However, if a new facility did locate in a nonattainment area to meet future demand for ethanol, it is assumed that it would be a 110 mgy facility that would have the potential to emit an additional 16 tpy of VOC and/or CO fugitive emissions.

It is important to note that most, if not all, ethanol fuel plants employ an active leak detection and repair (LDAR) program to minimize VOC emissions from tanks, valves, pumps and piping. (Docket No. EPA–HQ–OAR–2006–0089–0074). Fugitive particulate emissions from vehicular traffic are often controlled by a combination of paving and cleaning plant roads and other dust suppression methods. (Docket No. EPA–HQ–OAR–2006–0089–0074). Based on the assumption that there will be few, if any, facilities that will expand or be constructed in nonattainment areas in the future, and in light of the fugitive control measures that are employed at these facilities, we do not believe that this rulemaking will result in significant emissions increases in nonattainment areas.

4. Our Overall Conclusion

As stated previously, we believe that a larger, more economically efficient plant that is able to produce more ethanol fuel could result in significantly more fuel production without a corresponding increase in energy use or pollutant emissions, thereby resulting in a net reduction of environmental impacts as compared to the greater number of smaller, less efficient ethanol fuel production facilities that would be needed to achieve the same level of production. Given the likelihood of larger capacity facilities being better able to reduce emissions per gallon of ethanol produced than a greater number of smaller facilities, it is more logical to increase the capacity at a larger facility than locating additional smaller capacity facilities in an area. Similarly, it is more logical to allow the construction of larger capacity facilities in an area than locating numerous smaller capacity facilities in an area.

In conclusion, the effect of this rule is limited given that other emissions requirements continue to apply and will be unaffected by this rulemaking. As we have noted in our discussion, VOC and/or CO emissions (and other increases in emissions for NO_X and PM_{10}) will likely occur. However, other Federal regulations that apply will continue to apply to ethanol production facilities including numerous NSPS (*e.g.*, 40 CFR

[14] ICM., Air Dispersion Model Study. 100 TPY vs. 250 TPY. April 28, 2006, Attachment 3. (EPA–HQ–OAR–2006–0089–0086).

[15] ICM, Inc., Air Dispersion Modeling Study. 100 TPY vs. 250 TPY. April 28, 2006. Attachment 3. (EPA–HQ–OAR–2006–0089–0086, Attachment 3).

[16] Ability to change treatment of fugitives in individual PSD permits may be limited by the terms of such permits.

[17] Memorandum to Docket EPA–HQ–2006–0089. Spreadsheet Presenting Ethanol Production Facility Locations and Ozone Nonattainment Designations. April 2007.

[18] Where a stationary source is adding a emissions unit or modifying an existing emissions unit, the State's SIP-approved minor NSR program that permits physical modifications of existing minor sources would govern.

part 60, subparts Db, Dc (boilers and steam generating units); DD (grain handling and storage facilities); VV (leaks from VOC equipment); K, Ka, and Kb (storage vessels), and NESHAP (*e.g.*, 40 CFR part 63, subparts FFFF (miscellaneous organics. New Source Performance Standards require the application of the best demonstrated system of emission reductions for affected facilities to control criteria pollutants and NESHAP require the application of maximum achievable control technology to control HAP. We also note that nothing in this rule precludes a permitting authority from choosing to retain the 100 tpy major source threshold, as necessary, to meet its air quality needs. In short, we weighed and considered the environmental consequences of this rule relative to the expected benefits of ethanol use. The increased use of renewable fuels such as ethanol and biodiesel are expected to reduce dependence on foreign sources of petroleum, increase domestic sources of energy, and help transition to alternatives to petroleum in the transportation sector.

Comment: A couple of commenters stated that there will be an increased use of coal over natural gas to fuel the ethanol production process due to the higher cost of natural gas and the increased threshold. One commenter stated that many of the new ethanol fuel plants (which tend to be significantly larger than ethanol for human consumption plants) are considering using coal as a source of energy for the chemical processing instead of natural gas as the industry has traditionally used. The commenter expressed that the use of coal for production of ethanol fuel will result in much greater emissions of conventional pollutants such as NO_X, SO_2, and PM, as well as increases in toxic pollutants, such as mercury that are not expressly regulated by the PSD program. They also argued that the use of coal will result in increases in CO_2 emissions from ethanol plants which will threaten to undermine any global warming benefits of using ethanol instead of petroleum-derived fuels.

Response: We disagree with the assertion that existing ethanol production facilities that currently use natural gas as a fuel supply will likely convert to coal as a result of raising the major source threshold to 250 tpy. One commenter reported, and we agree, that the capital costs of such a conversion would be costly and facilities would more likely opt for increasing their production capacity. (Docket No. EPA–HQ–OAR–2006–0089–0086). The Renewable Fuels Association reports that, to their knowledge, no gas-fired mill has made a conversion to coal [EPA–HQ–OAR–2006–0089–0086]. It is acknowledged, however, that new plants may decide to use coal in lieu of natural gas because of the increased major source emissions threshold and because of it being a cheaper fuel source and that this could result in increases in emissions of pollutants not expressly regulated by the PSD program.

However, even if there is an increased use of coal, these facilities will be subject to the same PSD major source limit requirements as facilities that use natural gas, and will continue to be subject to other regulations (State and Federal). We also acknowledge that the use of coal could result in increases in CO_2 emissions from ethanol plants.

Comment: Several commenters provided specific examples of situations where implementation of our proposed Option could cause or contribute to the negative impact on an area.

One State commenter expressed that the proposed Option 1 would result in a negative impact on growth due to the projected increment consumption. They said that although some States could deal with this locally by making their regulations stricter than the Federal regulations, others are restricted because they have rules that limit them from having laws in their States that are stricter than the Federal rules.

A commenter representing State and local governments provided that even current minor sources—under the existing 100 tpy threshold, including fugitive emissions—are known to contribute significantly to potential violations of the NAAQS. They stated that permit data from STAPPA and ALAPCO members show that emissions from some ethanol fuel production facilities contribute to an area exceeding the 24-hour PM_{10} standard and, in some cases, are close to violating the 24-hour PM_{10} increment.

Another commenter stated that EPA and North Dakota have not resolved the issue of sulfur dioxide PSD exceedances in Class I areas of North Dakota and Montana, and that if Option 1 is promulgated for ethanol plants, there is potential for an increase of more than double the allowable sulfur dioxide emissions from proposed and existing ethanol plants.

Response: Generally, although we acknowledge that there may be negative impacts to particular regions or areas due to this rulemaking, we do not think there would be many instances where this is the case. Provided that there are local and regional instances with the potential for unacceptable negative impacts from this rule, a State or local government regulations/minor NSR program can be implemented to mitigate such impacts. In fact, a State is not required to adopt the rule's change in threshold and can maintain the 100 tpy threshold or other lower threshold in order to best serve its air quality/economic needs. If a State's regulations provide that its major source PSD thresholds cannot be more stringent than those prescribed by the Federal programs, its State minor NSR program should be able to address specific local concerns such as some of those suggested by the commenters.

We also acknowledge that there are local and Regional concerns that this rule is contrary to the purposes of the PSD program. It is true that one purpose of the PSD program is to ensure that new sources do not cause or contribute to an area that is in attainment becoming a nonattainment area. However, we believe that, in part, this directive will continue to be addressed by a State's minor NSR permit program and various Federal, State and Local air quality requirements. Federal regulations that apply and will continue to apply to ethanol production facilities include numerous NSPS (*e.g.*, 40 CFR part 60, subparts Db, Dc (boilers and steam generating units); DD (grain handling and storage facilities); VV (leaks from VOC equipment); K, Ka, and Kb (storage vessels), and NESHAP (*e.g.*, 40 CFR part 63, subparts FFFF (miscellaneous organics. New Source Performance Standards require the application of the best demonstrated system of emission reductions for affected facilities to control criteria pollutants and NESHAP require the application of maximum achievable control technology to control HAP.

F. Will there be a Federal ethanol-specific VOC emissions test protocol?

Comments: A couple of States argued that there is a need for a Federally-approved VOC performance test specifically for ethanol production. Reasons given include that (1) VOC testing at ethanol plants would be straightforward, (2) facilities would be assured of equitable treatment between them, (3) States would be able to more-easily and consistently determine compliance with Federal PSD rules, and (4) administering the Clean Air permitting programs for ethanol plants would be easier if there were a Federally-approved method to measure volatile organic compound emissions from ethanol plants.

Response: The EPA believes that the existing Reference Methods found at 40 CFR part 60 are applicable for

estimating the total mass emissions of VOCs, as defined in 40 CFR 51.100(s), from each process commonly used at wet and dry corn mills that produce ethanol. Over the past 5 years, VOC emissions from ethanol facilities under consent decrees with the United States have been successfully tested using a combination of EPA Reference Method 25 or 25A, and Reference Method 18.

In addition to the currently available Reference Methods, EPA works with industry groups to develop their own test methods as an alternative to using existing EPA Reference Methods, provided that the alternative methods produce accurate results. One example of an alternative method by an industry is the method developed by the Corn Refiners Association for measuring VOC emissions from the wet corn milling industry. This method was developed by the wet corn milling industry specifically to measure VOC mass emissions from processes within their facilities. It is a systematic approach for developing a specific list of target organic compounds and determining the appropriate sampling procedure to collect those target compounds during subsequent VOC emissions testing. This method is currently available on EPA's Emission Measurement Center Web page (*http://www.epa.gov/ttn/emc/prelim/otm11.pdf*). The EPA plans to begin a rulemaking in the near term regarding the above-noted new method. If promulgated, this method will be codified in 40 CFR part 51, appendix M, as a Federally-approved method for measuring VOC emissions from wet corn milling plants.

G. Are there backsliding issues related to this rulemaking?

Comments: Several commenters expressed concern that the States would not be able to adopt the proposed changes without violating the antibacksliding provisions under sections 193 of the CAA. The commenter alleges that the PSD program and ''synthetic minor'' limits are control requirements. Another commenter stated that states will have to comply with the anti-backsliding provisions of section 116 before adopting these changes. Finally, the same commenter noted that EPA's justification for the final rule appears inconsistent because we did not discuss the impacts of the proposed rule on state efforts to attain and maintain compliance with the NAAQS, as States will be required to do to adopt the changes under State law.

Response: Section 193 applies to nonattainment areas only. It provides that ''no control requirement in effect, or required to be adopted by an order, settlement agreement, or plan in effect before the date of the enactment of the CAA of 1990 may be changed unless the change insures equivalent or greater emission reductions of such air pollutant.'' We have previously stated our position that section 193 is ambiguous as to whether it applies to the NSR program, and that although we have chosen a conservative approach in our review of NSR SIP changes, our past option to review changes for consistency with section 193 is not conclusive of its scope. See 70 FR 39420, 69 FR 31056, 31063.

Recently, the U.S. Court of Appeals for the D.C. Circuit ruled on our interpretation of a similar, but not identical term ''controls'' as used in section 172(e), and found that ''NSR is a control.'' *South Coast Air Quality Mgmt. Dist.* v. *EPA*, 472 F.3d 882, 901 (D.C. Cir. 2006). We respectfully disagree with the court's finding on this issue and have filed a petition for rehearing of the decision. We also believe that the Court's interpretation of the term ''controls'' in section 172(e) is not necessarily decisive of how we should interpret the similar but different term ''control requirement'' in section 193, although we recognize we will need to take into account the D.C. Circuit's decision following the outcome of our rehearing request.

Nonetheless, this action does not in and of itself modify any requirements applicable to nonattainment areas. We believe the appropriate time to determine the applicability of and compliance with section 193 is when a control requirement in a nonattainment area is changed. For States that undertake a SIP revision, we will address the applicability of section 193 in our future actions to approve the SIP revisions. To the extent States can implement this approach consistent with their existing SIPs, the SIP requirements are not changing, and section 193 does not apply.

Similarly, we disagree with commenters that state that existing sources would simply be able to lift existing permit limits upon promulgation of this rule. These existing permit limits and other permit requirements remain in effect and enforceable unless and until revised through a permitting procedure which, to be consistent with CAA section 110(a)(2)(C) and 40 CFR 51.160, must be shown not to cause or contribute to a violation of the NAAQS and to comply with all applicable requirements.[19]

As explained previously, section 116 of the CAA allows States to enforce their own emissions limitation and standards if such requirements are not less stringent than the approved SIP and Federal regulations under sections 111 and 112 of the CAA. However, nothing in section 116 prevents a State from revising its SIP to make its requirements less stringent, provided the new requirements are not less stringent than Federal regulations under sections 111 and 112 and meet all other applicable requirements. Nothing in this rule authorizes States to adopt changes that are less stringent than what is required under sections 111 and 112, and therefore section 116 does not limit a State's ability to revise its SIP to adopt these changes.

Finally, in response to comments, we have analyzed the impact of this rule and discussed our findings in section IV.E. of this preamble.

VI. Effective Date of This Rule and Requirements for State or Tribal Implementation Plans and Title V

These changes will take effect in the Federal PSD and part 71 permit programs on July 2, 2007. This means that we will apply these rules in any area without a SIP-approved PSD program or title V program, for which we are the permitting authority, or for which we have delegated our authority to issues permits to a State, local, or tribal permitting authority.

We are establishing these requirements as minimum program elements of the PSD, nonattainment NSR, and title V programs. Notwithstanding this requirement, it may not be necessary for a State, local or tribal authority to revise its SIP or title V programs to begin to implement these changes. Some State, local or tribal authorities may be able to adopt these changes through a change in interpretation of the term ''chemical process plant'' without the need to revise the SIP or the title V program.

For any State, local or tribal agency that can implement the changes without revising its approved NSR or title V program, the changes will become effective when the permitting authority publicly announces that it has accepted these changes by interpretation. Although we find that no SIP or title V program revisions may be necessary in certain areas that are able to adopt these changes by interpretation, we encourage such State, local and tribal authorities in such areas to make such SIP or title V

[19] Where a stationary source is adding a emissions unit or modifying an existing emissions unit, the State's SIP-approved minor NSR program that permits physical modifications of existing minor sources would govern.

program changes in the future to enhance the clarity of the existing rules.

For areas that revise their SIPs or title V programs to adopt these changes, the changes are not effective in such area until we approve the SIP revision or title V program as meeting all applicable requirements. Revisions to title V programs to reflect the changes in this rule should be submitted to EPA for approval within 3 years. State, local, or tribal authorities may adopt or maintain NSR program elements that have the effect of making their regulations more stringent than these rules.

VII. Statutory and Executive Order Reviews

A. Executive Order 12866—Regulatory Planning and Review

Under Executive Order (EO) 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to Office of Management and Budget (OMB) review and the requirements of the Executive Order. Pursuant to the terms of Executive Order 12866, it has been determined that this rule is a ''significant regulatory action'' because it raises policy issues arising from the President's priorities. Also, this rule is not ''economically significant.''

Accordingly, the EPA submitted this action to OMB for review under Executive Order 12866 and any changes made in response to OMB's recommendations have been documented in the docket for this action.

B. Paperwork Reduction Act

This action does not impose any new information collection burden as the burden imposed by this rule has already been taken into account in previously-approved information collection requirement actions under both the NSR and title V programs. The OMB has previously approved the information collection requirements contained in the existing 40 CFR parts 51 and 52 regulations under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, and has assigned OMB control number 2060–0003, EPA ICR number 1230.17. The OMB has also previously approved the information collection requirements contained in the existing 40 CFR parts 70 and 71 regulations under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, and has assigned OMB control number 2060–0243 (EPA ICR number 1587.06) to the part 70 rule and OMB control number 2060–0336 (ICR Number 1713.05) to the part 71 rule respectively. A copy of the OMB-approved Information Collection Requests (ICR's), EPA ICR numbers 1230.17, 1587.06, and 1713.05, may be obtained from Susan Auby, Collection Strategies Division; U.S. Environmental Protection Agency (2822T); 1200 Pennsylvania Avenue, NW., Washington, DC 20460 or by calling (202) 566–1672.

It is necessary that certain records and reports be collected by a State or local agency (or the EPA Administrator in non-delegated areas), for example, to: (1) Confirm the compliance status of stationary sources, including identifying any stationary sources subject/not subject to the rule, and (2) ensuring that the stationary source control requirements are being achieved. The information is then used by the EPA or State enforcement personnel to ensure that the subject sources are applying the appropriate control technology and that the control requirements are being properly operated and maintained on a continuous basis. Based on the reported information, the State, local, or tribal agency can decide which plants, records, or processes should be inspected. Such information collection requirements for sources and States are currently reflected in the approved ICR's referenced above for the NSR and title V programs.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose, or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information; processing and maintaining information; disclosing and providing information; adjusting the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

C. Regulatory Flexibility Analysis

The Regulatory Flexibility Analysis (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the Agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of this action on small entities, a small entity is defined as: (1) A small business that is a small industrial entity as defined in the U.S. Small Business Administration (SBA) size standards (see 13 CFR 121.201); (2) a small governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000; or (3) a small organization that is any not-for-profit enterprise that is independently owned and operated and is not dominant in its field. There are an estimated 114 ethanol production facilities in the U.S. and an estimated 70 more under construction with several more being planned. Most of these facilities use corn as the primary feedstock. It is estimated that farmer-owned cooperatives make up nearly half of the ethanol plants in the U.S. with an additional percentage of facilities under construction that are locally-controlled. (*http://ethanol.org/production.html*). After considering the economic impacts of these final amendments on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. Note that the EPA does not know the number of ethanol plants that are (or will be) considered small entities; however, we believe this final rule will not have a significant economic impact on any ethanol plants because its overall impact will be to lessen the requirements that apply to such plants. Additionally, the expansion to additional feedstocks in the production of ethanol reduces the potential economic disparity among ethanol plants regardless of the carbohydrate feedstock used. Additionally, it is important to note that there are currently no commercial scale (other than commercial demonstration plants under construction for cellulosic biomass ethanol production) facilities using sugar beet, sugar cane, or cellulosic biomass feedstocks in the U.S.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA,

the EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any 1 year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation as to why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan.

The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements. This rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local, or tribal governments or the private sector.

The EPA has determined that this rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. Thus, this rule is not subject to the requirements of sections 202 and 205 of the UMRA.

E. Executive Order 13132—Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

Under section 6(b) of Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. Under section 6(c) of Executive Order 13132, EPA may not issue a regulation that has federalism implications and that preempts State law, unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

EPA has concluded that this final rule will not have federalism implications. It will not impose substantial direct compliance costs on State or local governments, nor will it preempt State law. Thus, the requirements of sections 6(b) and 6(c) of the Executive Order do not apply to this rule.

In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, the EPA specifically solicited comment on the proposed rule from State and local officials.

F. Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 13175, November 9, 2000), requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' This final rule does not have tribal implications, as specified in Executive Order 13175, as there are no tribal authorities currently issuing PSD, major nonattainment NSR, title V permits, or synthetic minor limits to ethanol plant which process carbohydrate feedstocks. Thus, Executive Order 13175 does not apply to this rule.

Although Executive Order 13175 does not apply to this final rule, EPA specifically solicited comment on the proposed rule from tribal officials.

G. Executive Order 13045—Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), applies to any rule that: (1) Is determined to be ''economically significant'' as defined under Executive Order 12866; and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of the Executive Order has the potential to influence the regulation. This final rule is not subject to Executive Order 13045 because it is not ''economically significant'' as defined in Executive Order 12866 and because the Agency does not have reason to believe the environmental health or safety risks addressed by this action present a disproportionate risk to children.

H. Executive Order 13211—Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

These final amendments do not constitute a ''significant energy action'' as defined in Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001), because they will not likely have a significant adverse effect on the supply, distribution, or use of energy.

I. National Technology Transfer and Advancement Act

As noted in the proposed rule, section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, 12(d) (15 U.S.C. 272 note), directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical.

Voluntary consensus standards are technical standards (for example, materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

These final rule amendments do not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

J. Executive Order 12898—Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629 (Feb. 16, 1994)) establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, any disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

The EPA has determined that this final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations. The reason for EPA's determination is because the final rule does not affect the level of protection provided to human health or the environment as it does not change a permitting authority's obligation to maintain the NAAQS, even though changes are being made to the PSD, major nonattainment NSR, and title V programs.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. These final rule amendments do not constitute a ''major rule'' as defined by 5 U.S.C. 804(2). Therefore, this rule will be effective July 2, 2007.

VIII. Judicial Review

Under section 307(b)(1) of the Act, judicial review of this final action is available by filing of a petition for review in the U.S. Court of Appeals for the District of Columbia Circuit by July 2, 2007. Any such judicial review is limited to only those objections that are raised with reasonable specificity in timely comments. Under section 307(b)(2) of the Act, the requirements of this final action may not be challenged later in civil or criminal proceedings brought by us to enforce these requirements.

List of Subjects

40 CFR Parts 51 and 52

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

40 CFR Parts 70 and 71

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: April 12, 2007.

Stephen L. Johnson,

Administrator.

■ For reasons stated in the preamble, title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 51—[AMENDED]

■ 1. The authority citation for part 51 continues to read as follows:

Authority: 23 U.S.C. 101; 42 U.S.C. 7401–7671q.

Subpart I—[Amended]

■ 2. Section 51.165 is amended by revising paragraphs (a)(1)(iv)(C)(*20*) and (a)(4)(xx) to read as follows:

§ 51.165 Permit requirements.

(a) * * *

(1) * * *

(iv) * * *

(C) * * *

(*20*) Chemical process plants—The term chemical processing plant shall not include ethanol production facilities that produce ethanol by natural fermentation included in NAICS codes 325193 or 312140;

* * * * *

(4) * * *

(xx) Chemical process plants—The term chemical processing plant shall not include ethanol production facilities that produce ethanol by natural fermentation included in NAICS codes 325193 or 312140;

* * * * *

■ 3. Section 51.166 is amended by revising paragraphs (b)(1)(i)(*a*), (b)(1)(iii)(*t*), and (i)(1)(ii)(*t*) to read as follows:

§ 51.166 Prevention of significant deterioration of air quality.

* * * * *

(b) * * *

(1)(i) * * *

(*a*) Any of the following stationary sources of air pollutants which emits, or has the potential to emit, 100 tons per year or more of any regulated NSR pollutant: Fossil fuel-fired steam electric plants of more than 250 million British thermal units per hour heat input, coal cleaning plants (with thermal dryers), kraft pulp mills, portland cement plants, primary zinc smelters, iron and steel mill plants, primary aluminum ore reduction plants (with thermal dryers), primary copper smelters, municipal incinerators capable of charging more than 250 tons of refuse per day, hydrofluoric, sulfuric, and nitric acid plants, petroleum refineries, lime plants, phosphate rock processing plants, coke oven batteries, sulfur recovery plants, carbon black plants (furnace process), primary lead smelters, fuel conversion plants, sintering plants, secondary metal production plants, chemical process plants (which does not include ethanol production facilities that produce ethanol by natural fermentation included in NAICS codes 325193 or 312140), fossil-fuel boilers (or combinations thereof) totaling more than 250 million British thermal units per hour heat input, petroleum storage and transfer units with a total storage capacity exceeding 300,000 barrels, taconite ore processing plants, glass fiber processing plants, and charcoal production plants;

* * * * *

(iii) * * *

(*t*) Chemical process plants—The term chemical processing plant shall not include ethanol production facilities that produce ethanol by natural fermentation included in NAICS codes 325193 or 312140;

* * * * *

(i) * * *

(1) * * *

(ii) * * *

(*t*) Chemical process plants—The term chemical processing plant shall not include ethanol production facilities that produce ethanol by natural fermentation included in NAICS codes 325193 or 312140;

* * * * *

Appendix S to Part 51—[Amended]

■ 4. Appendix S to Part 51 is amended by revising paragraphs II.A.4.(iii)(*t*), and II.F.(20) to read as follows:

Appendix S to Part 51—Emission Offset Interpretative Ruling

* * * * *

II. * * *
A. * * *
4. * * *
(iii) * * *
(*t*) Chemical process plants—The term chemical processing plant shall not include ethanol production facilities that produce ethanol by natural fermentation included in NAICS codes 325193 or 312140;
* * * * *
F. * * *
(20) Chemical process plants—The term chemical processing plant shall not include ethanol production facilities that produce ethanol by natural fermentation included in NAICS codes 325193 or 312140;
* * * * *

PART 52—[AMENDED]

■ 5. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401, *et seq.*

Subpart A—[Amended]

■ 6. Section 52.21 is amended by revising paragraphs (b)(1)(i)(*a*), (b)(1)(iii)(*t*) and (i)(1)(vii)(*t*) to read as follows:

§ 52.21 Prevention of significant deterioration of air quality.

* * * * *
(b) * * *
(1)(i) * * *
(*a*) Any of the following stationary sources of air pollutants which emits, or has the potential to emit, 100 tons per year or more of any regulated NSR pollutant: Fossil fuel-fired steam electric plants of more than 250 million British thermal units per hour heat input, coal cleaning plants (with thermal dryers), kraft pulp mills, portland cement plants, primary zinc smelters, iron and steel mill plants, primary aluminum ore reduction plants (with thermal dryers), primary copper smelters, municipal incinerators capable of charging more than 250 tons of refuse per day, hydrofluoric, sulfuric, and nitric acid plants, petroleum refineries, lime plants, phosphate rock processing plants, coke oven batteries, sulfur recovery plants, carbon black plants (furnace process), primary lead smelters, fuel conversion plants, sintering plants, secondary metal production plants, chemical process plants (which does not include ethanol production facilities that produce ethanol by natural fermentation included in NAICS codes 325193 or 312140), fossil-fuel boilers (or combinations thereof) totaling more than 250 million British thermal units per hour heat input, petroleum storage and transfer units with a total storage capacity exceeding 300,000 barrels, taconite ore processing plants, glass fiber processing plants, and charcoal production plants;
* * * * *
(iii) * * *
(*t*) Chemical process plants—The term chemical processing plant shall not include ethanol production facilities that produce ethanol by natural fermentation included in NAICS codes 325193 or 312140;
* * * * *
(i) * * *
(1) * * *
(vii) * * *
(*t*) Chemical process plants—The term chemical processing plant shall not include ethanol production facilities that produce ethanol by natural fermentation included in NAICS codes 325193 or 312140;
* * * * *

PART 70—[AMENDED]

■ 7. The authority citation for part 70 continues to read as follows:

Authority: 42 U.S.C 7401, *et seq.*

■ 8. Section 70.2 is amended by revising paragraph (2)(xx) of the definition of ''Major source'' to read as follows:

§ 70.2 Definitions.

* * * * *
Major source * * *
(2) * * *
(xx) Chemical process plants—The term chemical processing plant shall not include ethanol production facilities that produce ethanol by natural fermentation included in NAICS codes 325193 or 312140;
* * * * *

PART 71—[AMENDED]

■ 9. The authority citation for part 71 continues to read as follows:

Authority: 42 U.S.C 7401, *et seq.*

Subpart A—[Amended]

■ 10. Section 71.2 is amended by revising paragraph (2)(xx) of the definition of ''Major source'' to read as follows:

§ 71.2 Definitions.

* * * * *
Major source * * *
(2) * * *
(xx) Chemical process plants—The term chemical processing plant shall not include ethanol production facilities that produce ethanol by natural fermentation included in NAICS codes 325193 or 312140;
* * * * *

[FR Doc. E7–7365 Filed 4–30–07; 8:45 am]
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Federal Register

Tuesday,
May 1, 2007

Part V

Department of Housing and Urban Development

24 CFR Part 983
Project-Based Voucher Rents for Units Receiving Low-Income Housing Tax Credits; Proposed Rule

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 983

[Docket No. FR–5034–P–01]

RIN 2577–AC62

Project-Based Voucher Rents for Units Receiving Low-Income Housing Tax Credits

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the low-income housing tax credit (LIHTC) rent provisions of HUD's final Project-Based Voucher (PBV) program rule, which was published on October 13, 2005, and took effect on November 14, 2005. The October 13, 2005, final rule capped the PBV rents at the LIHTC rent in buildings with LIHTC units, even in cases where HUD formerly permitted such units to receive the higher rents permitted under the PBV program. After giving the issue further consideration, HUD now proposes to revert to the regulations that address this specific issue and were in effect prior to issuance of the October 13, 2005, final rule. The regulations in effect prior to the October 13, 2005, final rule did not necessarily require public housing agencies (PHAs) to cap section 8 maximum rents at the tax credit rent. PHAs may not enter into assistance contracts until HUD or an independent entity approved by HUD has conducted the required subsidy layering review and determined that the assistance is in accordance with HUD requirements.

DATES: *Comment Due Date:* July 2, 2007.

ADDRESSES: Interested persons are invited to submit comments regarding this proposed rule to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 10276, Washington, DC 20410–0500. Interested persons may also submit comments electronically through the federal electronic rulemaking portal at: *http://www.regulations.gov*. HUD strongly encourages commenters to submit their comments electronically through *http://www.regulations.gov*. The comments received through this portal are posted and can be easily viewed.

Facsimile (FAX) comments are not acceptable. All communications must refer to the docket number and title. All comments and communications submitted will be available, without revision, for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address. Due to security measures at the HUD Headquarters building, an advance appointment to review the public comments must be scheduled by calling the Regulations Division at (202) 708–3055 (this is not a toll-free number). Copies of the public comments submitted electronically are also available for inspection and downloading at *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: David Vargas, Director, Office of Voucher Programs, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 4210, Washington, DC 20410; telephone (202) 708–2815 (this is not a toll-free number). Persons with hearing or speech impairments may access these numbers via TTY by calling the Federal Information Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

On October 13, 2005, HUD published a final rule that comprehensively revised the regulations for HUD's PBV program, found in 24 CFR part 983. (See 70 FR 59892 *et seq.*) A detailed description of the legislative background and changes made to the program can be found in the preamble to the October 13, 2005, final rule.

Prior to the November 14, 2005, effective date of the October 13, 2005, final rule, PBV units with LIHTCs located outside of qualified census tracts could have rents set at the higher of 110 percent of the area fair market rent (FMR) or the LIHTC rent charged for comparable units in the same building that receive the tax credit and no other assistance. In other words, in areas where the tax credit rent was higher (*i.e.*, in the relatively lower-market-rent areas), the units would receive the benefit of that higher rent, but in areas where the FMR was higher (*i.e.*, in higher-market-rent areas), the units would not be capped at the tax credit rent and instead could receive the higher FMR-based rent.

The October 13, 2005, final rule changed this practice, in place for several years, under section 8(o)(13)(H) of the 1937 Act (42 U.S.C. 1437f(o)(13)(H)). The October 13, 2005, final rule provided, under § 983.304(c)(1)(v) and § 983.304(c)(2), that rent for units with tax credit may not exceed the tax credit rent in those cases where formerly, if the FMR-based rent were higher, that higher rent could be used.

Since the publication of the October 13, 2005, final rule, HUD received additional comments from PHAs and housing industry representatives expressing concern that the policy change regarding LIHTC units would impede rather than promote HUD's goal of increasing and preserving affordable housing, and requesting that HUD return to its original policy and position regarding LIHTC units. Some PHA and housing industry representatives also advised that the policy change may make many projects relying on LIHTCs non-viable because it could inhibit the financing of new projects by reducing the potential project rent, and thereby reduce the supply of low-income housing using LIHTCs.

After further consideration of this issue, HUD has determined that the policy change in the October 13, 2005, final rule concerning LIHTCs may not further HUD's mission to increase affordable housing as effectively as contemplated. While the change would cap federal subsidies, HUD hears the concerns that the change may inhibit the financing of new projects and possibly reduce, not increase, the supply of low-income housing using LIHTCs. HUD believes that concerns about excess federal subsidy may be adequately addressed using subsidy layering analysis. In this regard, HUD has determined that it would benefit by further public input on this issue.

This rule therefore proposes to reinstate the former policy in § 983.304(c) with respect to LIHTCs. In response to the public feedback received on the October 13, 2005, final rule, HUD has decided not to enforce § 983.304(c) as revised by the October 13, 2005, final rule. Instead, HUD will await further comment on this issue, as provided by this proposed rule, and will implement the final rule that results from this proposed rulemaking. In the meantime, owners who received a written notification of owner selection subsequent to the effective date of the final rule (November 14, 2005) and have entered into a Housing Assistance Payment (HAP) contract may request a redetermination of initial rents in accordance with § 983.301 of the final rule, if the initial rents were capped under the tax credit rent provision at § 983.304(c)(1)(v).

II. This Proposed Rule

For the reasons provided in Section I of this preamble, this proposed rule would remove the requirement added to § 983.304(c) by the October 13, 2005, final rule that PHAs in qualified census tracts have their rents limited by the tax credit rent. Therefore, PHAs would not

be required to reduce the PBV rent to the owner for LIHTC units merely because of the existence of LIHTCs. HUD or its designee would, however, conduct a subsidy layering review (consistent with longstanding HUD practice), which could result in rent reductions for projects with LIHTCs and PBV assistance. This review would be consistent with the prior policy. HUD is not proposing to revise or remove any other provision of the October 13, 2005, final rule.

III. Findings and Certifications

Executive Order 12866, Regulatory Planning and Review

The Office of Management and Budget (OMB) reviewed this proposed rule under Executive Order 12866 (entitled ''Regulatory Planning and Review''). OMB determined that this rule is a ''significant regulatory action,'' as defined in section 3(f) of the Executive Order (although not economically significant, as provided in section 3(f)(1) of the Executive Order). The docket file is available for public inspection between the hours of 8 a.m. and 5 p.m. in the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 10276, Washington, DC 20410–0500. Due to security measures at the HUD Headquarters building, an advance appointment to review the public comments must be scheduled by calling the Regulations Division at (202) 708–3055 (this is not a toll-free number).

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. This proposed rule, as with the prior rulemaking that led to the October 13, 2005, final rule, remains exclusively concerned with PHAs that have chosen to ''project-base'' 20 percent of their Housing Choice Voucher program assistance. Under the definition of ''Small governmental jurisdiction'' in section 601(5) of the RFA, the provisions of the RFA are applicable only to those few PHAs that are part of a political jurisdiction with a population of under 50,000 persons. There are very few small PHAs in that category. In addition, this rule would cover only an even smaller category of PHAs—those with PBV HAP contracts for units also receiving LIHTCs. The number of entities potentially affected by this rule is therefore not substantial.

Notwithstanding HUD's determination that this rule will not have a significant economic impact on a substantial number of small entities, HUD specifically invites comments regarding any less burdensome alternatives to this rule that will meet HUD's objectives as described by this preamble.

Environmental Impact

This interim rule involves establishment of external administrative or fiscal requirements related to a rate or cost determination, which does not constitute a development decision affecting the physical condition of specific project areas or building sites. Accordingly, under 24 CFR 50.19(c)(6), this interim rule is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*).

Executive Order 13132, Federalism

Executive Order 13132 (entitled ''Federalism'') prohibits, to the extent practicable and permitted by law, an agency from promulgating a regulation that has federalism implications and either imposes substantial direct compliance costs on state and local governments and is not required by statute, or preempts state law, unless the relevant requirements of section 6 of the Executive Order are met. This proposed rule does not have federalism implications and does not impose substantial direct compliance costs on state and local governments or preempt state law within the meaning of the Executive Order.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4; approved March 22, 1995) (UMRA) establishes requirements for federal agencies to assess the effects of their regulatory actions on state, local, and tribal governments, and on the private sector. This proposed rule does not impose any federal mandates on any state, local, or tribal governments, or on the private sector, within the meaning of the UMRA.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance number applicable to the program affected by this proposed rule is 14.871.

List of Subjects in 24 CFR Part 983

Grant programs—housing and community development, Housing, Low- and moderate-income housing, Rent subsidies, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, HUD proposes to amend 24 CFR part 983 to read as follows:

PART 983—PROJECT-BASED VOUCHER (PBV) PROGRAM

1. The authority citation for part 983 continues to read as follows:

Authority: 42 U.S.C. 1437f and 3535(d).

2. Revise § 983.304(c) to read as follows:

§ 983.304 Other subsidy: effect on rent to owner.

* * * * *

(c) *Subsidized projects.* (1) This paragraph (c) applies to any contract units in any of the following types of federally subsidized project:

(i) An insured or non-insured Section 236 project;

(ii) A formerly insured or non-insured Section 236 project that continues to receive Interest Reduction Payment following a decoupling action;

(iii) A Section 221(d)(3) below market interest rate (BMIR) project;

(iv) A Section 515 project of the Rural Housing Service;

(v) Any other type of federally subsidized project specified by HUD.

(2) The rent to owner may not exceed the subsidized rent (basic rent) as determined in accordance with requirements for the applicable federal program listed in paragraph (c)(1) of this section.

* * * * *

Dated: March 23, 2007.

Orlando J. Cabrera,

Assistant Secretary for Public and Indian Housing.

[FR Doc. E7–8135 Filed 4–30–07; 8:45 am]

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Federal Register

Tuesday,
May 1, 2007

Part VII

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 418

Medicare Program; Hospice Wage Index for Fiscal Year 2008; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 418

[CMS–1539–P]

RIN 0938–AO72

Medicare Program; Hospice Wage Index for Fiscal Year 2008

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would set forth the hospice wage index for fiscal year 2008. This proposed rule would also revise the methodology for updating the wage index for rural areas without hospital wage data and provide clarification of selected existing Medicare hospice regulations and policies.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on July 2, 2007.

ADDRESSES: In commenting, please refer to file code CMS–1539–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/eRulemaking.* Click on the link ''Submit electronic comments on CMS regulations with an open comment period.'' (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–1539–P, P.O. Box 8012, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–*1539*–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members. Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Terri Deutsch, (410) 786–9462.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–1539–P and the specific ''issue identifier'' that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.cms.hhs.gov/eRulemaking.* Click on the link ''Electronic Comments on CMS Regulations'' on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

A. General

1. Hospice Care

Hospice care is an approach to treatment that recognizes that the impending death of an individual warrants a change in the focus from curative care to palliative care for relief of pain and for symptom management. The goal of hospice care is to help terminally ill individuals continue life with minimal disruption to normal activities while remaining primarily in the home environment. A hospice uses an interdisciplinary approach to deliver medical, social, psychological, emotional, and spiritual services through use of a broad spectrum of professional and other caregivers, with the goal of making the individual as physically and emotionally comfortable as possible. Counseling services and inpatient respite services are available to the family of the hospice patient. Hospice programs consider both the patient and the family as a unit of care.

Section 1861(dd) of the Social Security Act (the Act) provides for coverage of hospice care for terminally ill Medicare beneficiaries who elect to receive care from a participating hospice. Section 1814(i) of the Act provides payment for Medicare participating hospices.

2. Medicare Payment for Hospice Care

Our regulations at 42 CFR part 418 establish eligibility requirements, payment standards and procedures, define covered services, and delineate the conditions a hospice must meet to be approved for participation in the Medicare program. Part 418 subpart G provides for payment in one of four prospectively-determined rate categories (routine home care, continuous home care, inpatient respite care, and general inpatient care) to hospices based on each day a qualified Medicare beneficiary is under a hospice election.

B. Hospice Wage Index

Our regulations at § 418.306(c) require each hospice's labor market to be established using the most current hospital wage data available, including any changes to the Metropolitan Statistical Areas (MSAs) definitions, which have been superseded by Core Based Statistical Areas (CBSAs). Section 1814(i)(2)(D) of the Act requires Medicare to pay for hospice care furnished in an individual's home on

the basis of the geographic location where the service is furnished. We have interpreted this to mean that the wage index value used is based upon the location of the beneficiary's home for routine home care and continuous home care and the location of the hospice agency for general inpatient and respite care.

The hospice wage index is used to adjust payment rates for hospice agencies under the Medicare program to reflect local differences in area wage levels. The original hospice wage index was based on the 1981 Bureau of Labor Statistics hospital data and had not been updated since 1983. In 1994, because of disparity in wages from one geographical location to another, a committee was formulated to negotiate a wage index methodology that could be accepted by the industry and the government. This committee, functioning under a process established by the Negotiated Rulemaking Act of 1990, was comprised of national hospice associations; rural, urban, large and small hospices; multi-site hospices; consumer groups; and a government representative. On April 13, 1995, the Hospice Wage Index Negotiated Rulemaking Committee signed an agreement for the methodology to be used for updating the hospice wage index.

In the August 8, 1997 **Federal Register** (62 FR 42860), we published a final rule implementing a new methodology for calculating the hospice wage index based on the recommendations of the negotiated rulemaking committee. The committee statement was included in the appendix of that final rule (62 FR 42883). The hospice wage index is updated annually. Our most recent annual update notice published in the September 1, 2006 **Federal Register** (71 FR 52080), set forth updates to the hospice wage index for FY 2007. On October 3, 2006, we published a correction notice in the **Federal Register** (71 FR 58415) and we published a subsequent correction notice on January 26, 2007 (72 FR 3856), to correct technical errors that appeared in the September 1, 2006 notice.

1. Changes to Core-Based Statistical Areas

The annual update to the hospice wage index is published in the **Federal Register** and is based on the most current available hospital wage data, as well as any changes by the Office of Management and Budget (OMB) to the definitions of MSAs. The August 4, 2005 final rule (70 FR 45130) set forth the adoption of the changes discussed in the OMB Bulletin No. 03–04 (June 6, 2003), which announced revised definitions for Micropolitan Statistical Areas and the creation of MSAs and Combined Statistical Areas. In adopting the OMB Core-Based Statistical Area (CBSA) geographic designations, we provided for a 1-year transition with a blended wage index for all providers for FY 2006. For FY 2006, the hospice wage index for each provider consisted of a blend of 50 percent of the FY 2006 MSA-based wage index and 50 percent of the FY 2006 CBSA-based wage index. As discussed in the August 4, 2005 final rule and in the September 1, 2006 notice, we will use the full CBSA-based wage index values as presented in Tables A and B of this proposed rule for FY 2008.

2. Raw Wage Index Values

Raw wage index values (that is, inpatient hospital pre-floor and pre-reclassified wage index values) as described in the August 8, 1997 hospice wage index final rule (62 FR 42860), are subject to either a budget neutrality adjustment or application of the wage index floor. Raw wage index values of 0.8 or greater are adjusted by the budget neutrality adjustment factor. Budget neutrality means that, in a given year, estimated aggregate payments for Medicare hospice services using the updated wage index values will equal estimated payments that would have been made for these services if the 1983 wage index values had remained in effect. To achieve this budget neutrality, the raw wage index is multiplied by a budget neutrality adjustment factor. The budget neutrality adjustment factor is calculated by comparing what we would have paid using current rates and the 1983 wage index to what would be paid using current rates and the new wage index. The budget neutrality adjustment factor is computed and applied annually. For the FY 2008 hospice wage index in the proposed rule, FY 2007 hospice payment rates were used in the budget neutrality adjustment factor calculation.

Raw wage index values below 0.8 are adjusted by the greater of: (1) The hospice budget neutrality adjustment factor; or (2) the hospice wage index floor (a 15 percent increase) subject to a maximum wage index value of 0.8. For example, if County A has a pre-floor, pre-reclassified hospital wage index (raw wage index value) of 0.4000, we would perform the following calculations using the budget neutrality factor (which for this example is 1.060988) and the hospice wage index floor to determine County A's hospice wage index:

Raw wage index value below 0.8 multiplied by the budget neutrality adjustment factor: (0.4000 x 1.060988 = 0.4244).

Raw wage index value below 0.8 multiplied by the hospice wage index floor: (0.4000 x 1.15 = 0.4600).

Based on these calculations, County A's hospice wage index would be 0.4600.

3. Hospice Payment Rates

Section 4441(a) of the Balanced Budget Act of 1997 (BBA) amended section 1814(i)(1)(C)(ii) of the Act to establish updates to hospice rates for FYs 1998 through 2002. Hospice rates were to be updated by a factor equal to the market basket index, minus 1 percentage point. However, neither the BBA nor subsequent legislation specified the market basket adjustment to be used to compute payment for FY 2008. Therefore, payment rates for FY 2008 will be updated according to section 1814(i)(1)(C)(ii)(VII) of the Act, which states that the update to the payment rates for subsequent FYs will be the market basket percentage for the fiscal year. Accordingly, the FY 2008 update to the payment rates will be the full market basket percentage increase for FY 2008. This rate update is implemented through a separate administrative instruction and is not part of this notice. Historically, the rate update has been published through a separate administrative instruction issued annually in July to provide adequate time to implement system change requirements. Providers determine their payment rates by applying the wage index in this notice to the labor portion of the published hospice rates.

4. Proxy for the Hospital Market Basket

As discussed above, the hospice payment rates are adjusted each year based upon the full hospital market basket. In the FY 2007 update notice (72 FR 52082) issued on September 1, 2006, we indicated that beginning in April 2006, with the publication of March 2006 data, the Bureau of Labor Statistic's (BLS's) Employment Cost Index (ECI) began using a different classification system, the North American Industrial Classification System (NAICS), instead of the Standard Industrial Classification System (SIC), which no longer exists. The ECIs had been used as the data source for wages and salaries and other price proxies in the hospital market basket. In the FY 2007 update notice we noted that no changes would be made to the usage of the NAICS-based ECI, however, input was solicited on this issue. We received

no comments and as a result, we are not proposing any changes.

II. Provisions of the Proposed Rule

A. Annual Update to the Hospice Wage Index

The hospice wage index presented in this proposed rule would be effective October 1, 2007 through September 30, 2008. We note that we are not proposing any modifications to the hospice wage index methodology. In accordance with our regulations and the agreement signed with other members of the Hospice Wage Index Negotiated Rulemaking Committee, we are using the most current hospital data available to us. For this proposed rule, the FY 2007 hospital wage index was the most current hospital wage data available for calculating the FY 2008 hospice wage index values. We used the FY 2007 pre-reclassified and pre-floor hospital area wage index data for this calculation.

Payment rates for each of the four levels of care are adjusted annually based upon the hospital market basket for that year and are promulgated administratively to allow for sufficient time for system changes and provider notification. Due to the need to ensure appropriate time for implementing changes, the latest adjustments to these payment rates were not incorporated into this proposed rule.

As noted above, for FY 2008, the hospice wage index values will be based solely on the adoption of the CBSA-based labor market definitions and its wage index. We continue to use the most recent pre-floor and pre-reclassified hospital wage index data available (FY 2003 hospital wage data).

A detailed description of the methodology used to compute the hospice wage index is contained in both the September 4, 1996 proposed rule (61 FR 46579) and the August 8, 1997 final rule (62 FR 42860). All wage index values are adjusted by a budget-neutrality factor of 1.066028 and are subject to the wage index floor adjustment, if applicable. We completed all of the calculations described in section 2.B below and included them in the wage index values reflected in Tables A and B of the Addendum. Specifically, Table A reflects the FY 2008 wage index values for urban areas under the CBSA designations. Table B reflects the FY 2008 wage index values for rural areas under the CBSA designations.

B. Rural Areas Without Hospital Wage Data

(If you choose to comment on issues in this section, please include the caption ''Rural Areas without Wage Data'' at the beginning of your comments.)

When adopting OMB's new labor market designations, we identified some geographic areas where there were no hospitals, and thus, no hospital wage index data on which to base the calculation of the hospice wage index (70 FR 45135, August 4, 2005). For FY 2006 and FY 2007, we adopted a policy to use the FY 2005 pre-floor, pre-reclassified hospital wage index value for rural areas when no rural hospital wage data were available. We also adopted the policy that for urban labor markets without an urban hospital from which a hospital wage index data could be derived, all of the CBSAs within the State would be used to calculate a statewide urban average wage index data to use as a reasonable proxy for these areas. We did not receive any public comments regarding our policy to calculate an urban wage index, using an average of all of the urban CBSA wage index data within the State, for urban labor markets without an urban hospital from which a hospital wage index could be derived. Consequently, in the August 2005 final rule and in the August 2006 update notice, we applied the average wage index data from all urban areas lacking hospital wage data in that state. Currently, the only CBSA that is affected by this is CBSA 25980 Hinesville-Fort Stewart, Georgia. We propose to continue this approach for urban areas where there are no hospitals and, thus, no hospital wage index data on which to base the calculations for the FY 2008 and subsequent hospice wage indexes. Therefore, the pre-floor, pre-reclassified wage index data for urban CBSA 25980, Hinesville-Fort Stewart, GA is calculated as the average wage index data of all urban areas in Georgia with a value of 0.9178.

Under the CBSA labor market areas, there are no rural hospitals in rural locations in Massachusetts and Puerto Rico. Since there was no rural proxy for more recent rural data within those areas, in the August 2005 proposed rule (70 FR 45135), we proposed applying the FY 2005 pre-floor, pre-reclassified hospital wage index value to rural areas where no hospital wage data are available. We did not receive any public comments on this matter, either. Consequently, in the August 2005 final rule and in the August 2006 update notice, we applied the FY 2005 pre-floor, pre-reclassified hospital wage index data for rural areas lacking hospital wage data in that state in both FY 2006 and FY 2007 for rural Massachusetts and rural Puerto Rico.

Since we have used the same wage index value from FY 2005 for these areas for the previous two fiscal years, we believe it is appropriate to consider alternatives in our methodology to update the wage index for rural areas without hospital wage index data. We believe that the best imputed proxy for rural areas, would: (1) Use pre-floor, pre-reclassified hospital data; (2) use the most local data available to impute a rural wage index; (3) be easy to evaluate; and, (4) be easy to update from year-to-year. Although our current methodology uses local, rural pre-floor, pre-reclassified hospital wage data, this method cannot be updated from year-to-year.

Therefore, in cases where there is a rural area without rural hospital wage data, we propose using the average pre-floor, pre-reclassified wage index data from all contiguous CBSAs to represent a reasonable proxy for the rural area. While this approach does not use rural data, it does use pre-floor, pre-reclassified hospital wage data, it is easy to evaluate, it is easy to update from year-to-year, and it uses the most local data available.

In determining an imputed rural wage index, we interpret the term contiguous to mean as sharing a border. For example, in the case of Massachusetts, the entire rural area consists of Dukes and Nantucket counties. We have determined that the borders of Dukes and Nantucket counties are contiguous with Barnstable and Bristol counties. Under the proposed methodology, the pre-floor, pre-reclassified wage index values for the counties of Barnstable (CBSA 12700, Barnstable Town, MA) of 1.2539 and Bristol (CBSA 39300, Providence-New Bedford-Fall River, RI-MA) of 1.0783 would be averaged resulting in an imputed pre-floor, pre-reclassified rural wage index of 1.1661 for rural Massachusetts for FY 2008. The impact of utilizing the proposed methodology is captured in the impact analysis (Table 1). As shown in Table B, the proposed wage index value for FY 2008 for rural Massachusetts is 1.2431. If we had retained the current methodology, the rural Massachusetts wage index would have been 1.0891.

While we believe that this policy could be readily applied to other rural areas that lack hospital wage data (possibly due to hospitals converting to a different provider type, such as a CAH, that do not submit the appropriate wage data), should a similar situation arise in the future, we may re-examine this policy.

However, we do not believe that this policy would be appropriate for Puerto Rico. There are sufficient economic

differences between hospitals in the United States and those in Puerto Rico, including the payment of hospitals in Puerto Rico using blended Federal/Commonwealth-specific rates that we believe that a separate and distinct policy for Puerto Rico is necessary. Consequently, any alternative methodology for imputing a wage index for rural Puerto Rico would need to take into account those differences. Our policy of imputing a rural wage index based on the wage index(es) of CBSAs contiguous to the rural area in question does not recognize the unique circumstances of Puerto Rico. While we have not yet identified an alternative methodology for imputing a wage index for rural Puerto Rico, we will continue to evaluate the feasibility of using existing hospital wage data and, possibly, wage data from other sources. Accordingly, we propose to continue using the most recent pre-floor, pre-reclassified wage index previously available for Puerto Rico, which is 0.4047.

C. Nomenclature Changes

(If you choose to comment on issues in this section, please include the caption ''Nomenclature Changes'' at the beginning of your comments.)

In the August 4, 2005 final rule and in the September 1, 2006 update notice, we noted that the Office of Management and Budget (OMB) published a bulletin that changed the titles to certain CBSAs. Since the publication of the Hospice FY 2006 update notice, OMB published additional bulletins that updated the CBSAs. Specifically, OMB added or deleted certain CBSA numbers and revised certain titles. Accordingly, in this proposed rule, we are proposing to clarify that this and all subsequent Hospice rules and notices are considered to incorporate the CBSA changes published in the most recent OMB bulletin, that applies to the hospital wage data used to determine the current hospice wage index. The proposed tables reflect changes made by these bulletins. The OMB bulletins may be accessed at *http://www.whitehouse.gov/omb/bulletins/index.html.*

D. Payment for Hospice Care Based on Location Where Care Is Furnished

(If you choose to comment on issues in this section, please include the caption ''Site of Service'' at the beginning of your comments)

Hospice providers receive payment for four levels of care based upon the individual's needs. Section 4442 of the BBA amended section 1814(i)(2) of the Act, effective for services furnished on or after October 1, 1997, required the application of the local wage index value of the geographic location at which the service is furnished for hospice care provided in the home. This provision has been codified in our regulations at 418.302(g). Prior to this provision, local wage index values were applied based on the geographic location of the hospice provider, regardless of where the hospice care was furnished. We believe that for the majority of hospice providers the office and the site for the provision of home and inpatient care occur in the same geographic area. However, with the substantial growth of hospice providers in multiple states and with multiple sites within a State, hospice providers have been able to inappropriately maximize reimbursement by locating their offices in high-wage areas and delivering services in a lower-wage area. We also believe that hospice providers are also able to inappropriately maximize reimbursement by locating their inpatient services either directly or under contractual arrangements in lower wage areas than their offices.

Section 4442 of the BBA applies the wage index value of a home's geographic location for services provided there, but is silent as to what wage index value should be used for hospice services provided in an inpatient setting. We believe that the application of the wage index values, for rate adjustments on the geographic area, where the hospice care is furnished provides a reimbursement rate that is a more accurate reflection of the wages paid by the hospice for the staff used to furnish care. We also believe that payment should reflect the location of the services provided and not the location of an office.

As a result, we are proposing that effective January 1, 2008, all payment rates (routine home care, continuous home care, inpatient respite and general inpatient care) be adjusted by the geographic wage index value of the area where hospice services are provided. In other words, the wage component of each payment rate is multiplied by the wage index value applicable to the location in which the hospice services are provided. We are proposing to amend 418.302(g) to reflect this proposed change.

Currently, hospice claims do not contain information identifying the location of the facility where general inpatient and respite care are provided. Therefore, we are unable to predict the savings or costs associated with the changes associated with this proposed provision. However, we believe that the impact of implementing this proposal will be negligible.

E. Clarification of Selected Existing Medicare Hospice Regulations and Policies

1. Educational Requirements for Nurse Practitioners

(If you choose to comment on issues in this section, please include the caption ''Nurse Practitioners'' at the beginning of your comments.)

On December 8, 2003, the Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 (Pub. L. 108–173). Section 408 of the MMA, Recognition of Attending Nurse Practitioners as Attending Physicians to Serve Hospice Patients, amended sections 1861(dd)(3)(B) and 1814(a)(7) of the Act to add nurse practitioners (NPs) to the definition of an attending physician for beneficiaries who have elected the hospice benefit. Section 408 of the MMA was implemented through an administrative issuance (Change Request (CR) 3226, Transmittals 22 and 304, September 24, 2004).

In the FY 2006 Final Rule (70 FR 45130, August 4, 2005), we revised § 418.3 to implement the provisions of section 408 of the MMA. Section 418.3 indicated (under clause (1)(ii) of the definition of ''attending physician'') that the nurse practitioner ''* * * meet the training, education, and experience requirements as the Secretary may prescribe * * *''. We believe that the definition for nurse practitioners under the Medicare hospice benefit should reflect the definition as established for the Medicare benefit found at § 410.75. To ensure consistency, we propose to revise the definition of ''attending physician'' at § 418.3 to cross reference the requirement in § 410.75(b).

2. Care Giver Breakdown and General Inpatient Care

(If you choose to comment on issues in this section, please include the caption ''Care Giver and General Inpatient Care'' at the beginning of your comments.)

The Medicare hospice benefit places emphasis on the provision of items and services to enable an individual to remain at home in the company of family and friends. Section 1861(dd)(1)(G) of the Act provides for short term inpatient hospice care to be available when an individual's pain and symptoms must be closely monitored or the intensity of interventions that are required cannot be provided in any other settings. In recognition of the stress in providing care for an

individual with a terminal diagnosis, inpatient respite care is available for family members, who serve as the primary caregivers, to obtain rest for a period of no more than five days at a time.

Medicare policy as described in chapter 9 of the Medicare Benefit Policy Manual, states that skilled nursing care may be required by a patient whose home support has broken down, if this breakdown makes it no longer feasible to furnish needed care in the home setting. If the hospice and the caregiver, working together, are no longer able to provide the necessary skilled nursing care in the individual's home, and if the individual's pain and symptom management can no longer be provided at home, then the individual may be eligible for a short term general inpatient level of care. However, it has come to our attention that some hospice providers are requesting payment for the ''general inpatient'' level of care for circumstances that do not qualify under the statute, our regulations at § 418.202(e) or Medicare hospice policy. In other words, some hospices are billing Medicare for ''caregiver breakdown'' at the higher ''general inpatient'' level, rather than the lower payment for ''inpatient respite'' or ''routine home care'' levels of care.

To receive payment for ''general inpatient care'' under the Medicare hospice benefit, beneficiaries *must* require an intensity of care directed towards pain control and symptom management that cannot be managed in any other setting. While there is nothing prohibiting a Medicare approved facility from serving as the individual's home, it is the level of care provided to meet the individual's needs which determine payment rates for Medicare services. ''Caregiver breakdown'' should not be billed as ''general inpatient care'' regardless of where services are provided, unless the intensity-of-care requirement is met. If the individual is no longer able to remain in his or her home, but the required care does not meet the requirements for ''general inpatient care'', hospices should bill this care as ''inpatient respite care'', payable for no more than 5 days, until alternative arrangements can be made.

As explained, this is a clarification of current Medicare policy and is not anticipated to create new limitations on access to hospice care. However, we are clarifying that the level of care provided, not the location of care, is what determines the appropriate level of payment. Additionally, the circumstances addressed with this policy, and the clarification discussed above, should not be construed as similar to situations where an individual does not have family or friends or other means that are able to take on the role of a caregiver when a hospice election is made. The Medicare hospice benefit provides for care that is medically reasonable and necessary for the palliation and management of the terminal and related conditions, and is structured in such a way to enable the individual with a terminal condition to remain at home, as long as possible, in the company of family and friends. We recognize the difficulties surrounding the provision of hospice care to an individual who is terminally ill and who does not have caregivers at home. This may be a challenge in rural areas. Section 409 of the MMA established the Rural Hospice Demonstration which hopes to test alternative mechanisms for providing hospice services for beneficiaries who lack an appropriate caregiver and who reside in rural areas. However, we intend to monitor the usage of the general inpatient care.

We are providing this as clarification and therefore are not proposing any changes in existing statute, regulation or policy manual.

3. Certification of Terminal Illness

(If you choose to comment on issues in this section, please include the caption ''Certification'' at the beginning of your comments.)

Section 1814(a)(7)(A)(i) of the Act stipulates that the individual's attending physician and the hospice medical director initially certify the individual's terminal diagnosis with prognosis of six months or less if the disease runs its normal course. The requirements of the physician certification, including supportive documentation were discussed in the hospice care amendment proposed rule (67 CFR 70363) and final rule (70 CFR 70548). In these rules, we indicated that a direct consultation between the hospice medical director and the attending physician was not a requirement and that information supporting the terminal diagnosis could be obtained through the hospice admission nurse. We are aware that the intent of this has been construed by some providers, to permit the admission nurse, utilizing documents such as local coverage decisions, to determine eligibility for hospice services and certify the individual's terminal diagnosis. This interpretation is incorrect. We have permitted the hospice nurses to obtain information to be used by the hospice medical director as part of the medical documents used in his or her determination of the terminal diagnosis and eligibility for the Medicare hospice benefit. The statute is explicit in the requirement that the physician and medical director determine the prognosis and his or her signature on the certification attests to that fact. We will provide further clarification in administrative instructions.

III. Collection of Information Requirements

This document does not impose any information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132. We estimated the impact on hospices, as a result of the proposed changes to the FY 2008 hospice wage index. As discussed previously, the methodology for computing the wage index was determined through a negotiated rulemaking committee and implemented in the August 8, 1997 final rule (62 FR 42860). This proposed rule updates the hospice wage index in accordance with our regulation and that methodology, incorporating the adoption of the CBSA designations used in the FY 2007 hospital wage index data.

<bullet≤ Table 1 categorizes the impact on hospices by various geographic and provider characteristics. We estimate that the total hospice payments will decrease $538,000 as a result of the proposed FY 2008 wage index values. We anticipate that the final rule will more accurately project payment for FY 2008, based upon changes in the wage index values.

<bullet≤ Table A reflects the FY 2008 wage index values for urban areas designations.

<bullet≤ Table B reflects the FY 2008 wage index values for rural areas designations.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We have determined that this notice is not an economically significant rule under this Executive Order.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospices and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6.5 million to $31.5 million in any 1 year (for details, see the Small Business Administration's regulation at 65 FR 69432, that sets forth size standards for health care industries). For purposes of the RFA, most hospices are small entities. As indicated in Table 1 below, there are 2,819 hospices. Approximately 81 percent of Medicare certified hospices are identified as voluntary, government, or other agencies and, therefore, are considered small entities. Because the National Hospice and Palliative Care Organization estimates that approximately 79 percent of hospice patients are Medicare beneficiaries, we have not considered other sources of revenue in this analysis. Furthermore, the wage index methodology was previously determined by consensus, through a negotiated rulemaking committee that included representatives of national hospice associations; rural, urban, large and small hospices; multi-site hospices; and consumer groups. Based on all of the options considered, the committee agreed on the methodology described in the committee statement, and it was adopted into regulation in the August 8, 1997 final rule. In developing the process for updating the wage index in the 1997 final rule, we considered the impact of this methodology on small entities and attempted to mitigate any potential negative effects.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a CBSA and has fewer than 100 beds. We have determined that this notice would not have a significant impact on the operations of a substantial number of small rural hospitals. We are not preparing an analysis for the RFA because we have determined that this rule will not have a significant economic impact on a substantial number of small entities.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, and tribal governments, in the aggregate, or by the private sector, of $120 million or more. This notice is not anticipated to have an effect on State, local, or tribal governments or on the private sector of $120 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this notice under the threshold criteria of Executive Order 13132, Federalism, and have determined that it would not have an impact on the rights, roles, and responsibilities of State, local, or tribal governments.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

B. Anticipated Effects

We are unable to quantify the extent of the usage of the general inpatient level of care in the event of caregiver breakdown and are, therefore, unable to definitively anticipate the impact of our clarification of the general inpatient level of care policy in the event of caregiver breakdown. For this reason, we solicit comment on what the impact of our clarification might be. Based on anecdotal evidence as well as substantial increases in the number of claims submitted for general inpatient care, however, we believe a small proportion of patient days attributed to general inpatient care would be appropriately allocated to inpatient respite care with this clarification. Significant savings could be realized even if only a small proportion of patient days attributed to general inpatient care were allocated to inpatient respite care.

For example, to determine the impact of allocating 5.0 percent of general inpatient care days to inpatient respite care, we used the FY 2005 patient days, expenditures and number of beneficiaries electing the hospice benefit to estimate the impact of the clarification of existing policy in this proposed rule. The number of inpatient days was adjusted from 1,250,678 to 1,188,144. The number of inpatient respite days was adjusted from 96,646 to 159,180. While inpatient respite expenditures increased from $14,000,000 to $23,058,570, general inpatient care expenditures decreased from $737,300,000 to $700,435,000. In total, if 5.0 percent of patient days that were attributed to general inpatient care in FY 2005 were allocated to the inpatient respite level of care, it would have resulted in net savings of $27,806,430.

The impact analysis of this notice represents the projected effects of the changes in the hospice wage index from FY 2007 to FY 2008. We estimate the effects by estimating payments for FY 2008 utilizing the FY 2007 wage index values and the full implementation of the CBSA designations while holding all other payment variables constant.

We note that certain events may combine to limit the scope or accuracy of our impact analysis, because such an analysis is future oriented and, thus, susceptible to forecasting errors due to other changes in the forecasted impact time period. The nature of the Medicare program is such that the changes may interact, and the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon hospices.

For the purposes of this proposed rule, we compared estimated payments using the FY 1983 hospice wage index to estimated payments using the FY 2008 wage index and determined the hospice wage index to be budget neutral. Budget neutrality means that, in a given year, estimated aggregate payments for Medicare hospice services using the FY 2008 wage index would equal estimated aggregate payments that would have been made for the same services if the 1983 wage index had remained in effect. Budget neutrality to 1983 does not imply that estimated payments would not increase since the

budget neutrality applies only to the wage index portion and not the total payment rate, which accommodates inflation.

As discussed above, we use the latest claims file available to us to develop the impact table when we issue the annual yearly wage index update. For the purposes of this proposed rule, data were obtained from the National Claims History file using FY 2005 claims processed through June 2006, which were the most recent available data. We deleted bills from hospice providers that have since closed. For the purposes of this proposed rule, this file is adequate to demonstrate the impact of the FY 2008 wage index values and is not intended to project the anticipated expenditures for FY 2008. We anticipate that the final rule will more accurately project payment for FY 2008. This impact analysis compares hospice payments using the FY 2007 hospice wage index to the estimated payments using the FY 2008 wage index. We note that estimated payments for FY 2008 are determined by using the wage index for FY 2008 and payment rates for FY 2007. As noted in previous sections, payment rates for FY 2008 are published through administrative issuance.

Table 1 demonstrates the results of our analysis. In column 1 we indicate the number of hospices included in our analysis. In column 2, we indicate the number of routine home care days that were included in our analysis, although the analysis was performed on all types of hospice care. Column 3 estimates payments using the FY 2007 wage index values and the FY 2007 payment rates. Column 4 estimates payments using FY 2008 wage index values as well as the FY 2007 payment rates. Column 5 compares columns 3 and 4 and shows the percentage change in estimated hospice payments made based on the hospice category.

Table 1 also categorizes hospices by various geographic and provider characteristics. The first row displays the aggregate result of the impact for all Medicare-certified hospices. The second and third rows of the table categorize hospices according to their geographic location (urban and rural). Our analysis indicated that there are 1,858 hospices located in urban areas and 961 hospices located in rural areas. The next two groupings in the table indicate the number of hospices by census region, also broken down by urban and rural hospices. The sixth grouping shows the impact on hospices based on the size of the hospice's program. We determined that the majority of hospice payments are made at the routine home care rate. Therefore, we based the size of each individual hospice's program on the number of routine home care days provided in FY 2006. The next grouping shows the impact on hospices by type of ownership. The final grouping shows the impact on hospices defined by whether they are provider-based or freestanding. As indicated in Table 1 below, there are 2,819 hospices. Approximately 81 percent of Medicare-certified hospices are identified as voluntary, government, or other agencies and, therefore, are considered small entities. Because the National Hospice and Palliative Care Organization estimates that approximately 79 percent of hospice patients are Medicare beneficiaries, we have not considered other sources of revenue in this analysis. Furthermore, the wage index methodology was previously determined by consensus, through a negotiated rulemaking committee that included representatives of national hospice associations; rural, urban, large, and small hospices; multi-site hospices; and consumer groups. Based on all of the options considered, the committee agreed on the methodology described in the committee statement, and it was adopted into regulation in the August 8, 1997 final rule. In developing the process for updating the wage index in the 1997 final rule, we considered the impact of this methodology on small entities and attempted to mitigate any potential negative effects.

As stated previously, the following discussions are limited to demonstrating trends rather than projected dollars. We used the CBSA designations and wage indices as well as the data from FY 2005 claims processed through June 2006 in developing the impact analysis. For FY 2008 the wage index is the variable that differs between the FY 2007 payments and the FY 2008 estimated payments. FY 2007 payment rates are used for both FY 2007 actual payments and the FY 2008 estimated payments. The FY 2008 payment rates will be adjusted to reflect the full FY 2007 hospital market basket, as required by section 1814(i)(1)(C)(ii)(VII) of the Act. As previously noted, we publish these rates through administrative issuances.

As discussed in the FY 2006 final rule (70 FR 45129), hospice agencies may utilize multiple wage indices to compute their payments based on potentially different geographic locations of the beneficiary for routine and continuous home care or the CBSA for the location of the hospice agency for respite and general inpatient care. For this analysis, we use payments to the hospice in the aggregate based on the location of the hospice. The impact of hospice wage index changes have been analyzed according to the type of hospice, geographic location, type of ownership, hospice base, and size.

Our analysis shows that most hospices are in urban areas and provide the vast majority of routine home care days. Most hospices are medium sized followed by large hospices. Hospices are almost equal in numbers by ownership with 1,231 designated as non-profit and 1,265 as proprietary. The vast majority of hospices are freestanding.

1. Hospice Size

Under the Medicare hospice benefit, hospices can provide four different levels of care days. The majority of the days provided by a hospice are routine home care days (RHC) representing over 70 percent of the services provided by a hospice. Therefore, the number of routine home care days can be used as a proxy for the size of the hospice, that is, the more days of care provided, the larger the hospice. As discussed in the August 4, 2005 final rule, we currently use three size designations to present the impact analyses. The three categories are: Small agencies having 0 to 3,499 RHC days; medium agencies having 3,500 to 19,999 RHC days; and large agencies having 20,000 or more RHC days. Using RHC days as a proxy for size, our analysis indicates that the proposed FY 2008 wage index values are anticipated to have virtually no impact on hospice providers, with a slight decrease of 0.1 percent anticipated for small hospices while no change is anticipated for medium or large hospices.

2. Geographic Location

Our analysis demonstrates that the proposed FY 2008 wage index values will result in little change in estimated payments with urban hospices anticipated to experience no change while rural hospices are anticipated to experience a slight increase of 0.2 percent. The greatest increase of 0.9 percent is anticipated to be experienced by the Mountain regions, followed by an increase for East North Central of 0.6 percent and Pacific regions of 0.5 percent. The remaining urban regions are anticipated to experience a decrease ranging from 0.6 percent in the East South Central region to 0.1 percent in the Middle Atlantic region. The greatest decrease of 2.6 percent is anticipated for Puerto Rico.

For rural hospices, the South Atlantic region and Puerto Rico are anticipated to experience no change. Two regions are anticipated to experience a decrease of 0.9 percent for New England and 0.4 percent for the mountain regions. The

remaining regions are anticipated to experience an increase ranging from 0.2 percent for the East North Central region to 0.6 percent for the Middle Atlantic and East South Central regions.

3. Type of Ownership

By type of ownership, non-profit hospices are anticipated to experience no change in payment while government hospices are anticipated to experience a slight increase of 0.1 percent. Slight decreases are anticipated for proprietary hospices of 0.1 percent and 0.2 percent for other categories.

4. Hospice Base

For hospice-based facilities, a decrease of 0.1 percent in payment is anticipated for freestanding facilities. Home health, hospital and skilled nursing facilities area anticipated to experience an increase of 0.1, 0.2 and 0.7 percent respectively.

BILLING CODE 4120–01–P

TABLE 1.--IMPACT OF HOSPICE WAGE INDEX CHANGES

	Number of Hospices (1)	Number of Routine Home Care Days in Thousands (2)	Payments using FY 2007 Wage Index in Thousands (3)	Estimated Payments using FY 2008 Wage Index in thousands (4)	Percent Change in Hospice Payments (5)
ALL HOSPICES	2,819	53,696	8,050,709	8,050,171	0.0%
URBAN HOSPICES	1,858	46,120	7,096,555	7,093,707	0.0%
RURAL HOSPICES	961	7,576	954,154	956,465	0.2%
BY REGION – URBAN:					
NEW ENGLAND	108	1,524	271,214	269,900	-0.5%
MIDDLE ATLANTIC	189	4,450	726,343	725,493	-0.1%
SOUTH ATLANTIC	259	9,895	1,607,162	1,599,320	-0.5%
EAST NORTH CENTRAL	277	6,661	1,020,561	1,026,738	0.6%
EAST SOUTH CENTRAL	143	3,773	509,258	506,298	-0.6%
WEST NORTH CENTRAL	137	2,976	409,772	409,274	-0.1%
WEST SOUTH CENTRAL	326	6,461	914,938	910,550	-0.5%
MOUNTAIN	163	3,928	612,959	618,209	0.9%
PACIFIC	222	5,793	965,445	970,559	0.5%
PUERTO RICO	34	659	58,903	57,367	-2.6%
BY REGION – RURAL:					
NEW ENGLAND	26	131	19,034	18,855	-0.9%
MIDDLE ATLANTIC	43	380	48,781	49,061	0.6%
SOUTH ATLANTIC	122	1,412	180,566	180,530	0.0%
EAST NORTH CENTRAL	138	980	127,906	128,156	0.2%
EAST SOUTH CENTRAL	134	1,768	214,476	215,735	0.6%
WEST NORTH CENTRAL	183	833	106,150	106,730	0.5%
WEST SOUTH CENTRAL	159	1,172	136,955	137,307	0.3%
MOUNTAIN	104	559	72,484	72,188	-0.4%
PACIFIC	51	334	47,214	47,314	0.2%
PUERTO RICO	1	7	588	588	0.0%
ROUTINE HOME CARE DAYS:					
0 - 3499 DAYS (small)	692	1,119	151,253	151,155	-0.1%
3500–19,999 DAYS (medium)	1,327	13,199	1,846,717	1,847,453	0.0%
20,000+ DAYS (large)	800	39,378	6,052,738	6,051,564	0.0%
TYPE OF OWNERSHIP:					
VOLUNTARY	1,231	25,501	3,941,228	3,943,177	0.0%
PROPRIETARY	1,265	25,527	3,715,943	3,713,812	-0.1%
GOVERNMENT	194	915	123,604	123,747	0.1%
OTHER	129	1,753	269,934	269,436	-0.2%

	Number of Hospices (1)	Number of Routine Home Care Days in Thousands (2)	Payments using FY 2007 Wage Index in Thousands (3)	Estimated Payments using FY 2008 Wage Index in thousands (4)	Percent Change in Hospice Payments (5)
HOSPICE BASE:					
FREESTANDING	1,622	39,054	5,850,352	5,846,059	-0.1%
HOME HEALTH AGENCY	622	8,249	1,237,212	1,238,470	0.1%
HOSPITAL	562	6,214	934,307	936,616	0.2%
SKILLED NURSING FACILITY	13	179	28,837	29,026	0.7%

Note: FY 2007 payment rates were used for estimated payments for FY 2008. FY 2008 payment rates will be adjusted to reflect the full hospital market basket and will be promulgated through administrative issuance.

C. Conclusion

Our impact analysis compared hospice payments by using the FY 2007 wage index to the estimated payments using the FY 2008 wage index. Through the analysis, we estimate that total hospice payments will effectively be budget neutral with a negligible decrease from FY 2007 by $538,000. Additionally, we compared estimated payments using the FY 1983 hospice wage index to estimated payments using the FY 2008 wage index and determined the current hospice wage index to be budget neutral, as required by the negotiated rulemaking committee. As noted above, the payment rates used reflect the FY 2007 rates. The FY 2008 payment rates will be adjusted to reflect the full FY 2008 hospital market basket, as required by section 1814(i)(1)(C)(ii)(VII) of the Act. We publish these rates through administrative issuances.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects for 42 CFR Part 418

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services would amend 42 CFR part 418 as set forth below:

PART 418—HOSPICE CARE

1. The authority citation for part 418 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—General Provision and Definitions

2. Section 418.3 is amended by revising paragraph (1)(ii) in the definition of ''attending physician'' to read as follows:

§ 418.3 Definitions.

* * * * *

Attending Physician means a—(1)(i) * * *

(ii) Nurse practitioner who meets the training, education, and experience requirements as described in § 410.75 (b).

* * * * *

Subpart G—Payment for Hospice Care

3. Section 418.302 is amended by revising paragraph (g) to read as follows:

§ 418.302 Payment procedures for hospice care.

* * * * *

(g) Payment for routine home care, continuous home care, general inpatient care and inpatient respite care is made on the basis of the geographic location where the services are provided.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: March 15, 2007.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: April 11, 2007.

Michael O. Leavitt,

Secretary.

BILLING CODE: 4120–01–P

Note: The following Addendum will not appear in the Code of Federal Regulations.

ADDENDUM

TABLE A--HOSPICE WAGE INDEX FOR URBAN AREAS BY CBSA

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
10180	Abilene, TX Callahan, TX Jones, TX Taylor, TX	0.8528
10380	Aguadilla-Isabela-San Sebastián, PR Aguada, PR Aguadilla, PR Moca, PR Isabela, PR Lares, PR Rincón, PR San Sebastián, PR Anasco, PR	0.4502
10420	Akron, OH Portage, OH Summit, OH	0.9225
10500	Albany, GA Dougherty, GA Lee, GA Baker, GA Terrell, GA Worth, GA	0.9585
10580	Albany-Schenectady-Troy, NY Albany, NY Rensselaer, NY Saratoga, NY Schenectady, NY Schoharie, NY	0.9296
10740	Albuquerque, NM Bernalillo, NM Sandoval, NM Valencia, NM Torrance, NM	1.0082

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
10780	Alexandria, LA Rapides, LA Grant, LA	0.8535
10900	Allentown-Bethlehem-Easton, PA-NJ Carbon, PA Lehigh, PA Northampton, PA Warren, NJ	1.0604
11020	Altoona, PA Blair, PA	0.9394
11100	Amarillo, TX Potter, TX Randall, TX Armstrong, TX Carson, TX	0.9774
11180	Ames, IA Story, IA	1.0404
11260	Anchorage, AK Anchorage, AK Matanuska-Susitna, AK	1.2817
11300	Anderson, IN Madison, IN	0.9254
11340	Anderson, SC Anderson, SC	0.9612
11460	Ann Arbor, MI Washtenaw, MI	1.1541
11500	Anniston-Oxford, AL Calhoun, AL	0.8283
11540	Appleton, WI Calumet, WI Outagamie, WI	1.0079
11700	Asheville, NC Buncombe, NC Madison, NC Haywood, NC Henderson, NC	0.9825

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
12020	Athens-Clarke County, GA Clarke, GA Madison, GA Oconee, GA Oglethorpe, GA	1.0507
12060	Atlanta-Sandy Springs-Marietta, GA Barrow, GA Bartow, GA Carroll, GA Cherokee, GA Clayton, GA Cobb, GA Coweta, GA De Kalb, GA Douglas, GA Fayette, GA Forsyth, GA Fulton, GA Gwinnett, GA Henry, GA Newton, GA Paulding, GA Pickens, GA Rockdale, GA Spalding, GA Walton, GA Butts, GA Dawson, GA Haralson, GA Heard, GA Jasper, GA Lamar, GA Meriwether, GA Pike, GA	1.0407
12100	Atlantic City, NJ Atlantic, NJ	1.2612
12220	Auburn-Opelika, AL Lee, AL	0.8631

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
12260	Augusta-Richmond County, GA-SC	1.0305
	Aiken, SC	
	Columbia, GA	
	Edgefield, SC	
	McDuffie, GA	
	Richmond, GA	
	Burke, GA	
12420	Austin-Round Rock, TX	0.9961
	Bastrop, TX	
	Caldwell, TX	
	Hays, TX	
	Travis, TX	
	Williamson, TX	
12540	Bakersfield, CA	1.1433
	Kern, CA	
12580	Baltimore-Towson, MD	1.0754
	Anne Arundel, MD	
	Baltimore, MD	
	Baltimore City, MD	
	Carroll, MD	
	Harford, MD	
	Howard, MD	
	Queen Anne's, MD	
12620	Bangor, ME	1.0352
	Penobscot, ME	
12700	Barnstable Town, MA	1.3367
12940	Barnstable, MA	0.8618
	Baton Rouge, LA	
	Ascension, LA	
	East Baton Rouge Parish, LA	
	Livingston, LA	
	West Baton Rouge Parish, LA	
	East Feliciana, LA	
	Iberville, LA	
	Pointe Coupee, LA	
	St. Helena, LA	
	West Feliciana, LA	
12980	Battle Creek, MI	1.0407
	Calhoun, MI	

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
13020	Bay City, MI Bay, MI	0.9862
13140	Beaumont-Port Arthur, TX Hardin, TX Jefferson, TX Orange, TX	0.9163
13380	Bellingham, WA Whatcom, WA	1.1837
13460	Bend, OR Deschutes, OR	1.1452
13644	Bethesda-Gaithersburg-Frederick, MD Frederick, MD Montgomery, MD	1.1623
13740	Billings, MT Carbon, MT Yellowstone, MT	0.9287
13780	Binghamton, NY Broome, NY Tioga, NY	0.9366
13820	Birmingham-Hoover, AL Blount, AL Jefferson, AL Shelby, AL St. Clair, AL Bibb, AL Chilton, AL Walker, AL	0.9481
13900	Bismarck, ND Burleigh, ND Morton, ND	0.8000
13980	Blacksburg-Christiansburg-Radford, VA Giles, VA Montgomery, VA Pulaski, VA Radford City, VA	0.8755
14020	Bloomington, IN Greene, IN Owen, IN Monroe, IN	0.9096

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
14060	Bloomington-Normal, IL McLean, IL	0.9535
14260	Boise City-Nampa, ID Ada, ID Canyon, ID Boise, ID Gem, ID Owyhee, ID	1.0022
14484	Boston-Quincy, MA Norfolk, MA Plymouth, MA Suffolk, MA	1.2450
14500	Boulder, CO Boulder, CO	1.1033
14540	Bowling Green, KY Edmonson, KY Warren, KY	0.8686
14740	Bremerton-Silverdale, WA Kitsap, WA	1.1634
14860	Bridgeport-Stamford-Norwalk, CT Fairfield, CT	1.3495
15180	Brownsville-Harlingen, TX Cameron, TX	1.0053
15260	Brunswick, GA Brantley, GA Glynn, GA McIntosh, GA	1.0835
15380	Buffalo-Niagara Falls, NY Erie, NY Niagara, NY	1.0046
15500	Burlington, NC Alamance, NC	0.9247
15540	Burlington-South Burlington, VT Chittenden, VT Franklin, VT Grand Isle, VT	1.0100
15764	Cambridge-Newton-Framingham, MA Middlesex, MA	1.1694

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
15804	Camden, NJ Burlington, NJ Camden, NJ Gloucester, NJ	1.1078
15940	Canton-Massillon, OH Carroll, OH Stark, OH	0.9627
15980	Cape Coral-Fort Myers, FL Lee, FL	0.9959
16180	Carson City, NV Carson City, NV	1.0687
16220	Casper, WY Natrona, WY	0.9749
16300	Cedar Rapids, IA Linn, IA Benton, IA Jones, IA	0.9475
16580	Champaign-Urbana, IL Champaign, IL Ford, IL Piatt, IL	1.0281
16620	Charleston, WV Kanawha, WV Putnam, WV Boone, WV Clay, WV Lincoln, WV	0.9106
16700	Charleston-North Charleston, SC Berkeley, SC Charleston, SC Dorchester, SC	0.9749
16740	Charlotte-Gastonia-Concord, NC-SC Cabarrus, NC Gaston, NC Mecklenburg, NC Union, NC York, SC Anson, NC	1.0185

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
16820	Charlottesville, VA Albemarle, VA Charlottesville City, VA Fluvanna, VA Greene, VA Nelson, VA	1.0794
16860	Chattanooga, TN-GA Catoosa, GA Dade, GA Hamilton, TN Marion, TN Walker, GA Sequatchie, TN	0.9539
16940	Cheyenne, WY Laramie, WY	0.9658
16974	Chicago-Naperville-Joliet, IL Cook, IL De Kalb, IL Du Page, IL Grundy, IL Kane, IL Kendall, IL McHenry, IL Will, IL	1.1461
17020	Chico, CA Butte, CA	1.1783

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
17140	Cincinnati-Middletown, OH-KY-IN Boone, KY Brown, OH Campbell, KY Clermont, OH Dearborn, IN Gallatin, KY Grant, KY Hamilton, OH Kenton, KY Ohio, IN Pendleton, KY Warren, OH Franklin, IN Bracken, KY Butler, OH	1.0235
17300	Clarksville, TN-KY Christian, KY Montgomery, TN Stewart, TN Trigg, KY	0.8993
17420	Cleveland, TN Bradley, TN Polk, TN	0.8644
17460	Cleveland-Elyria-Mentor, OH Cuyahoga, OH Geauga, OH Lake, OH Lorain, OH Medina, OH	1.0021
17660	Coeur d'Alene, ID Kootenai, ID	0.9961
17780	College Station-Bryan, TX Brazos, TX Burleson, TX Robertson, TX	0.9642
17820	Colorado Springs, CO El Paso, CO Teller, CO	1.0342

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
17860	Columbia, MO Boone, MO Howard, MO	0.9106
17900	Columbia, SC Lexington, SC Richland, SC Calhoun, SC Fairfield, SC Kershaw, SC Saluda, SC	0.9523
17980	Columbus, GA-AL Chattahoochee, GA Harris, GA Muscogee, GA Russell, AL Marion, GA	0.8783
18020	Columbus, IN Bartholomew, IN	0.9933
18140	Columbus, OH Delaware, OH Fairfield, OH Franklin, OH Licking, OH Madison, OH Pickaway, OH Morrow, OH Union, OH	1.0774
18580	Corpus Christi, TX Nueces, TX San Patricio, TX Aransas, TX	0.9129
18700	Corvallis, OR Benton, OR	1.2308
19060	Cumberland, MD-WV Allegany, MD Mineral, WV	0.9004

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
19124	Dallas-Plano-Irving, TX Collin, TX Dallas, TX Denton, TX Ellis, TX Hunt, TX Kaufman, TX Rockwall, TX Delta, TX	1.0740
19140	Dalton, GA Murray, GA Whitfield, GA	0.9693
19180	Danville, IL Vermilion, IL	0.9878
19260	Danville, VA Danville City, VA Pittsylvania, VA	0.9009
19340	Davenport-Moline-Rock Island, IA-IL Henry, IL Rock Island, IL Scott, IA Mercer, IL	0.9430
19380	Dayton, OH Greene, OH Miami, OH Montgomery, OH Preble, OH	0.9634
19460	Decatur, AL Lawrence, AL Morgan, AL	0.8698
19500	Decatur, IL Macon, IL	0.8712
19660	Deltona-Daytona Beach-Ormond Beach, FL Volusia, FL	0.9875

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
19740	Denver-Aurora, CO Adams, CO Arapahoe, CO Broomfield, CO Denver, CO Douglas, CO Jefferson, CO Clear Creek, CO Elbert, CO Gilpin, CO Park, CO	1.1652
19780	Des Moines, IA Dallas, IA Polk, IA Warren, IA Guthrie, IA Madison, IA	0.9822
19804	Detroit-Livonia-Dearborn, MI Wayne, MI	1.0960
20020	Dothan, AL Geneva, AL Henry, AL Houston, AL	0.8000
20100	Dover, DE Kent, DE	1.0497
20220	Dubuque, IA Dubuque, IA	0.9736
20260	Duluth, MN-WI Douglas, WI St. Louis, MN Carlton, MN	1.0705
20500	Durham, NC Chatham, NC Durham, NC Orange, NC Person, NC	1.0475
20740	Eau Claire, WI Chippewa, WI Eau Claire, WI	1.0266

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
20764	Edison, NJ Middlesex, NJ Somerset, NJ Monmouth, NJ Ocean, NJ	1.1929
20940	El Centro, CA Imperial, CA	0.9675
21060	Elizabethtown, KY Hardin, KY Larue, KY	0.9271
21140	Elkhart-Goshen, IN Elkhart, IN	1.0048
21300	Elmira, NY Chemung, NY	0.8784
21340	El Paso, TX El Paso, TX	0.9651
21500	Erie, PA Erie, PA	0.9410
21604	Essex County, MA Essex, MA	1.1106
21660	Eugene-Springfield, OR Lane, OR	1.1594
21780	Evansville, IN-KY Gibson, IN Henderson, KY Posey, IN Vanderburgh, IN Warrick, IN Webster, KY	0.9670
21820	Fairbanks, AK Fairbanks North Star, AK	1.1789
21940	Fajardo, PR Ceiba, PR Fajardo, PR Luquillo, PR	0.4641
22020	Fargo, ND-MN Cass, ND Clay, MN	0.8795
22140	Farmington, NM San Juan, NM	0.9156

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
22180	Fayetteville, NC Cumberland, NC Hoke, NC	0.9536
22220	Fayetteville-Springdale-Rogers, AR-MO Benton, AR Washington, AR Madison, AR McDonald, MO	0.9450
22380	Flagstaff, AZ Coconino, AZ	1.2367
22420	Flint, MI Genesee, MI	1.1693
22500	Florence, SC Darlington, SC Florence, SC	0.8942
22520	Florence-Muscle Shoals, AL Colbert, AL Lauderdale, AL	0.8361
22540	Fond Du Lac, WI Fond Du Lac, WI	1.0727
22660	Fort Collins-Loveland, CO Larimer, CO	1.0174
22744	Ft Lauderdale-Pompano Beach-Deerfield Beach, FL Broward, FL	1.0802
22900	Fort Smith, AR-OK Crawford, AR Sebastian, AR Sequoyah, OK Franklin, AR Le Flore, OK	0.8241
23020	Fort Walton Beach-Crestview-Destin, FL Okaloosa, FL	0.9214
23060	Fort Wayne, IN Allen, IN Wells, IN Whitley, IN	1.0145

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
23104	Fort Worth-Arlington, TX Johnson, TX Parker, TX Tarrant, TX Wise, TX	1.0201
23420	Fresno, CA Fresno, CA	1.1666
23460	Gadsden, AL Etowah, AL	0.8599
23540	Gainesville, FL Alachua, FL Gilchrist, FL	0.9890
23580	Gainesville, GA Hall, GA	0.9549
23844	Gary, IN Lake, IN Porter, IN Jasper, IN Newton, IN	0.9950
24020	Glens Falls, NY Warren, NY Washington, NY	0.8874
24140	Goldsboro, NC Wayne, NC	0.9777
24220	Grand Forks, ND-MN Grand Forks, ND Polk, MN	0.8474
24300	Grand Junction, CO Mesa, CO	1.0306
24340	Grand Rapids-Wyoming, MI Kent, MI Barry, MI Ionia, MI Newaygo, MI	1.0079
24500	Great Falls, MT Cascade, MT	0.9166
24540	Greeley, CO Weld, CO	1.0236

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
24580	Green Bay, WI Brown, WI Kewaunee, WI Oconto, WI	1.0433
24660	Greensboro-High Point, NC Guilford, NC Randolph, NC Rockingham, NC	0.9451
24780	Greenville, NC Pitt, NC Greene, NC	1.0055
24860	Greenville, SC Greenville, SC Pickens, SC Laurens, SC	1.0451
25020	Guayama, PR Arroyo, PR Guayama, PR Patillas, PR	0.3720
25060	Gulfport-Biloxi, MS Hancock, MS Harrison, MS Stone, MS	0.9504
25180	Hagerstown-Martinsburg, MD-WV Washington, MD Morgan, WV Berkeley, WV	0.9635
25260	Hanford-Corcoran, CA Kings, CA	1.0961
25420	Harrisburg-Carlisle, PA Cumberland, PA Dauphin, PA Perry, PA	1.0023
25500	Harrisonburg, VA Harrisonburg City, VA Rockingham, VA	0.9672

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
25540	Hartford-West Hartford-East Hartford, Hartford, CT Litchfield, CT Middlesex, CT Tolland, CT	1.1613
25620	Hattiesburg, MS Forrest, MS Lamar, MS Perry, MS	0.8000
25860	Hickory-Lenoir-Morganton, NC Alexander, NC Burke, NC Caldwell, NC Catawba, NC	0.9605
25980	Hinesville-Fort Stewart, GA Liberty, GA Long, GA	0.9784
26100	Holland-Grand Haven, MI Ottawa, MI	0.9768
26180	Honolulu, HI Honolulu, HI	1.1829
26300	Hot Springs, AR Garland, AR	0.9362
26380	Houma-Bayou Cane-Thibodaux, LA Lafourche, LA Terrebonne, LA	0.8616
26420	Houston-Sugar Land-Baytown, TX Chambers, TX Fort Bend, TX Harris, TX Liberty, TX Montgomery, TX Waller, TX Austin, TX San Jacinto, TX Brazoria, TX Galveston, TX	1.0669

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
26580	Huntington-Ashland, WV-KY-OH Boyd, KY Cabell, WV Greenup, KY Lawrence, OH Wayne, WV	0.9591
26620	Huntsville, AL Limestone, AL Madison, AL	0.9602
26820	Idaho Falls, ID Bonneville, ID Jefferson, ID	0.9688
26900	Indianapolis, IN Boone, IN Hamilton, IN Hancock, IN Hendricks, IN Johnson, IN Marion, IN Morgan, IN Shelby, IN Brown, IN Putnam, IN	1.0548
26980	Iowa City, IA Johnson, IA Washington, IA	1.0355
27060	Ithaca, NY Tompkins, NY	1.0584
27100	Jackson, MI Jackson, MI	1.0191
27140	Jackson, MS Hinds, MS Madison, MS Rankin, MS Copiah, MS Simpson, MS	0.8817
27180	Jackson, TN Chester, TN Madison, TN	0.9438

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
27260	Jacksonville, FL Clay, FL Duval, FL Nassau, FL St. johns, FL Baker, FL	0.9770
27340	Jacksonville, NC Onslow, NC	0.8774
27500	Janesville, WI Rock, WI	1.0293
27620	Jefferson City, MO Callaway, MO Cole, MO Moniteau, MO Osage, MO	0.8882
27740	Johnson City, TN Carter, TN Unicoi, TN Washington, TN	0.8574
27780	Johnstown, PA Cambria, PA	0.9189
27860	Jonesboro, AR Craighead, AR Poinsett, AR	0.8168
27900	Joplin, MO Jasper, MO Newton, MO	0.9173
28020	Kalamazoo-Portage, MI Kalamazoo, MI Van Buren, MI	1.1411
28100	Kankakee-Bradley, IL Kankakee, IL	1.0749

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
28140	Kansas City, MO-KS Cass, MO Clay, MO Clinton, MO Jackson, MO Johnson, KS Lafayette, MO Leavenworth, KS Miami, KS Platte, MO Ray, MO Wyandotte, KS Franklin, KS Linn, KS Bates, MO Caldwell, MO	1.0122
28420	Kennewick-Richland-Pasco, WA Benton, WA Franklin, WA	1.1026
28660	Killeen-Temple-Fort Hood, TX Bell, TX Coryell, TX Lampasas, TX	0.9489
28700	Kingsport-Bristol-Bristol, TN-VA Bristol city, VA Hawkins, TN Scott, VA Sullivan, TN Washington, VA	0.8512
28740	Kingston, NY Ulster, NY	0.9985
28940	Knoxville, TN Anderson, TN Blount, TN Knox, TN Loudon, TN Union, TN	0.8794
29020	Kokomo, IN Howard, IN Tipton, IN	1.0307

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
29100	La Crosse, WI-MN Houston, MN La Crosse, WI	1.0048
29140	Lafayette, IN Benton, IN Carroll, IN Tippecanoe, IN	0.9521
29180	Lafayette, LA Lafayette, LA St. Martin, LA	0.8836
29340	Lake Charles, LA Calcasieu, LA Cameron, LA	0.8437
29404	Lake County-Kenosha County, IL-WI Lake, IL Kenosha, WI	1.1268
29460	Lakeland, FL Polk, FL	0.9465
29540	Lancaster, PA Lancaster, PA	1.0222
29620	Lansing-East Lansing, MI Clinton, MI Eaton, MI Ingham, MI	1.0754
29700	Laredo, TX Webb, TX	0.8327
29740	Las Cruces, NM Dona Ana, NM	0.9885
29820	Las Vegas-Paradise, NV Clark, NV	1.2185
29940	Lawrence, KS Douglas, KS	0.8917
30020	Lawton, OK Comanche, OK	0.8598
30140	Lebanon, PA Lebanon, PA	0.9252
30300	Lewiston, ID-WA Nez Perce, ID Asotin, WA	1.0504

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
30340	Lewiston-Auburn, ME Androscoggin, ME	0.9729
30460	Lexington-Fayette, KY Bourbon, KY Clark, KY Fayette, KY Jessamine, KY Scott, KY Woodford, KY	0.9787
30620	Lima, OH Allen, OH	0.9639
30700	Lincoln, NE Lancaster, NE Seward, NE	1.0758
30780	Little Rock-North Little Rock, AR Faulkner, AR Lonoke, AR Pulaski, AR Saline, AR Grant, AR Perry, AR	0.9477
30860	Logan, UT-ID Cache, UT Franklin, ID	0.9618
30980	Longview, TX Gregg, TX Upshur, TX Rusk, TX	0.9368
31020	Longview, WA Cowlitz, WA	1.0672
31084	Los Angeles-Long Beach-Santa Ana, CA Los Angeles, CA	1.2536

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
31140	Louisville, KY-IN Bullitt, KY Clark, IN Floyd, IN Harrison, IN Jefferson, KY Oldham, KY Washington, IN Henry, KY Meade, KY Nelson, KY Shelby, KY Spencer, KY Trimble, KY	0.9720
31180	Lubbock, TX Lubbock, TX Crosby, TX	0.9182
31340	Lynchburg, VA Amherst, VA Bedford, VA Bedford City, VA Campbell, VA Lynchburg City, VA Appomattox, VA	0.9268
31420	Macon, GA Bibb, GA Jones, GA Twiggs, GA Crawford, GA Monroe, GA	1.0148
31460	Madera, CA Madera, CA	0.8692
31540	Madison, WI Dane, WI Columbia, WI Iowa, WI	1.1556
31700	Manchester-Nashua, NH Hillsborough, NH Merrimack, NH	1.0919

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
31900	Mansfield, OH Richland, OH	0.9883
32420	Mayagüez, PR Hormigueros, PR Mayagüez, PR	0.4425
32580	McAllen-Edinburg-Mission, TX Hidalgo, TX	0.9352
32780	Medford, OR Jackson, OR	1.1532
32820	Memphis, TN-MS-AR Crittenden, AR DeSoto, MS Fayette, TN Shelby, TN Tipton, TN Marshall, MS Tate, MS Tunica, MS	0.9992
32900	Merced, CA Merced, CA	1.2228
33124	Miami-Miami Beach-Kendall, FL Miami-Dade, FL	1.0460
33140	Michigan City-La Porte, IN La Porte, IN	0.9720
33260	Midland, TX Midland, TX	1.0432
33340	Milwaukee-Waukesha-West Allis, WI Milwaukee, WI Ozaukee, WI Washington, WI Waukesha, WI	1.0893

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
33460	Minneapolis-St. Paul-Bloomington, MN-WI	1.1669
	Anoka, MN	
	Carver, MN	
	Chisago, MN	
	Dakota, MN	
	Hennepin, MN	
	Isanti, MN	
	Pierce, WI	
	Ramsey, MN	
	Scott, MN	
	Sherburne, MN	
	St. Croix, WI	
	Washington, MN	
	Wright, MN	
33540	Missoula, MT	0.9517
	Missoula, MT	
33660	Mobile, AL	0.8435
	Mobile, AL	
33700	Modesto, CA	1.2503
	Stanislaus, CA	
33740	Monroe, LA	0.8525
	Ouachita, LA	
	Union, LA	
33780	Monroe, MI	1.0348
	Monroe, MI	
33860	Montgomery, AL	0.8538
	Autauga, AL	
	Elmore, AL	
	Montgomery, AL	
	Lowndes, AL	
34060	Morgantown, WV	0.8979
	Monongalia, WV	
	Preston, WV	
34100	Morristown, TN	0.8457
	Grainger, TN	
	Hamblen, TN	
	Jefferson, TN	
34580	Mount Vernon-Anacortes, WA	1.1211
	Skagit, WA	

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
34620	Muncie, IN Delaware, IN	0.9127
34740	Muskegon-Norton Shores, MI Muskegon, MI	1.0597
34820	Myrtle Beach-Conway-North Myrtle Beach, SC Horry, SC	0.9392
34900	Napa, CA Napa, CA	1.4257
34940	Naples-Marco Island, FL Collier, FL	1.0597
34980	Nashville-Davidson-Murfreesboro, TN Cheatham, TN Davidson, TN Dickson, TN Robertson, TN Rutherford, TN Sumner, TN Williamson, TN Wilson, TN Cannon, TN Hickman, TN Macon, TN Smith, TN Trousdale, TN	1.0497
35004	Nassau-Suffolk, NY Nassau, NY Suffolk, NY	1.3498
35084	Newark-Union, NJ-PA Pike, PA Essex, NJ Morris, NJ Sussex, NJ Union, NJ Hunterdon, NJ	1.2677
35300	New Haven-Milford, CT New Haven, CT	1.2742

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
35380	New Orleans-Metairie-Kenner, LA Jefferson, LA Orleans, LA Plaquemines, LA St. Bernard, LA St. Charles, LA St. John Baptist, LA St. Tammany, LA	0.9414
35644	New York-White Plains-Wayne, NY-NJ Bronx, NY Kings, NY New York, NY Putnam, NY Queens, NY Richmond, NY Rockland, NY Westchester, NY Bergen, NJ Passaic, NJ Hudson, NJ	1.4047
35660	Niles-Benton Harbor, MI Berrien, MI	0.9504
35980	Norwich-New London, CT New London, CT	1.2720
36084	Oakland-Fremont-Hayward, CA Alameda, CA Contra Costa, CA	1.6863
36100	Ocala, FL Marion, FL	0.9452
36140	Ocean City, NJ Cape May, NJ	1.1163
36220	Odessa, TX Ector, TX	1.0738
36260	Ogden-Clearfield, UT Davis, UT Weber, UT Morgan, UT	0.9589

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
36420	Oklahoma City, OK Canadian, OK Cleveland, OK Logan, OK McClain, OK Oklahoma, OK Grady, OK Lincoln, OK	0.9427
36500	Olympia, WA Thurston, WA	1.1813
36540	Omaha-Council Bluffs, NE-IA Cass, NE Douglas, NE Pottawattamie, IA Sarpy, NE Washington, NE Harrison, IA Mills, IA Saunders, NE	1.0074
36740	Orlando-Kissimmee, FL Lake, FL Orange, FL Osceola, FL Seminole, FL	1.0076
36780	Oshkosh-Neenah, WI Winnebago, WI	0.9930
36980	Owensboro, KY Daviess, KY Hancock, KY Mc Lean, KY	0.9326
37100	Oxnard-Thousand Oaks-Ventura, CA Ventura, CA	1.2308
37340	Palm Bay-Melbourne-Titusville, FL Brevard, FL	1.0067
37460	Panama City-Lynn Haven, FL Bay, FL	0.8557

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
37620	Parkersburg-Marietta-Vienna, WV-OH Pleasants, WV Wirt, WV Washington, OH Wood, WV	0.8504
37700	Pascagoula, MS George, MS Jackson, MS	0.8757
37860	Pensacola-Ferry Pass-Brent, FL Escambia, FL Santa Rosa, FL	0.8528
37900	Peoria, IL Peoria, IL Tazewell, IL Woodford, IL Marshall, IL Stark, IL	0.9575
37964	Philadelphia, PA Bucks, PA Chester, PA Delaware, PA Montgomery, PA Philadelphia, PA	1.1722
38060	Phoenix-Mesa-Scottsdale, AZ Maricopa, AZ Pinal, AZ	1.0966
38220	Pine Bluff, AR Jefferson, AR Cleveland, AR Lincoln, AR	0.8937
38300	Pittsburgh, PA Allegheny, PA Beaver, PA Butler, PA Fayette, PA Washington, PA Westmoreland, PA Armstrong, PA	0.9247
38340	Pittsfield, MA Berkshire, MA	1.0944

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
38540	Pocatello, ID Bannock, ID Power, ID	1.0021
38660	Ponce, PR Juana Diaz, PR Ponce, PR Villalba, PR	0.5568
38860	Portland-South Portland-Biddeford, ME Cumberland, ME Sagadahoc, ME York, ME	1.0562
38900	Portland-Vancouver-Beaverton, OR-WA Clackamas, OR Clark, WA Columbia, OR Multnomah, OR Washington, OR Yamhill, OR Skamania, WA	1.2170
38940	Port St. Lucie-Fort Pierce, FL Martin, FL St. Lucie, FL	1.0482
39100	Poughkeepsie-Newburgh-Middletown, NY Dutchess, NY Orange, NY	1.1631
39140	Prescott, AZ Yavapai, AZ	1.0485
39300	Providence-New Bedford-Fall River, RI-MA Bristol, MA Bristol, RI Kent, RI Newport, RI Providence, RI Washington, RI	1.1495
39340	Provo-Orem, UT Utah, UT Juab, UT	1.0167
39380	Pueblo, CO Pueblo, CO	0.9331

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
39460	Punta Gorda, FL Charlotte, FL	1.0026
39540	Racine, WI Racine, WI	0.9974
39580	Raleigh-Cary, NC Franklin, NC Johnston, NC Wake, NC	1.0515
39660	Rapid City, SD Pennington, SD Meade, SD	0.9416
39740	Reading, PA Berks, PA	1.0257
39820	Redding, CA Shasta, CA	1.4069
39900	Reno-Sparks, NV Washoe, NV Storey, NV	1.2753
40060	Richmond, VA Charles City, VA Chesterfield, VA Colonial Heights City, VA Dinwiddie, VA Goochland, VA Hanover, VA Henrico, VA Hopewell City, VA New Kent, VA Petersburg City, VA Powhatan, VA Prince George, VA Richmond City, VA Amelia, VA Caroline, VA Cumberland, VA King and Queen, VA King William, VA Louisa, VA Sussex, VA	0.9783

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
40140	Riverside-San Bernardino-Ontario, CA Riverside, CA San Bernardino, CA	1.1624
40220	Roanoke, VA Craig, VA Franklin, VA Botetourt, VA Roanoke, VA Roanoke City, VA Salem City, VA	0.9218
40340	Rochester, MN Olmsted, MN Dodge, MN Wabasha, MN	1.2161
40380	Rochester, NY Livingston, NY Monroe, NY Ontario, NY Orleans, NY Wayne, NY	0.9588
40420	Rockford, IL Boone, IL Winnebago, IL	1.0649
40484	Rockingham County, NH Rockingham, NH Strafford, NH	1.0830
40580	Rocky Mount, NC Edgecombe, NC Nash, NC	0.9439
40660	Rome, GA Floyd, GA	0.9800
40900	Sacramento--Arden-Arcade--Roseville, CA El Dorado, CA Placer, CA Sacramento, CA Yolo, CA	1.4255
40980	Saginaw-Saginaw Township North, MI Saginaw, MI	0.9460

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
41060	St. Cloud, MN Benton, MN Stearns, MN	1.1046
41100	St. George, UT Washington, UT	0.9877
41140	St. Joseph, MO-KS Andrew, MO Buchanan, MO Doniphan, KS De Kalb, MO	1.0786
41180	St. Louis, MO-IL Clinton, IL Franklin, MO Jefferson, MO Jersey, IL Lincoln, MO Madison, IL Monroe, IL St. Charles, MO St. Clair, IL St. Louis, MO St. Louis City, MO Warren, MO Bond, IL Calhoun, IL Macoupin, IL Crawford, MO Washington, MO	0.9600
41420	Salem, OR Marion, OR Polk, OR	1.1127
41500	Salinas, CA Monterey, CA	1.5284
41540	Salisbury, MD Somerset, MD Wicomico, MD	0.9544
41620	Salt Lake City, UT Salt Lake, UT Summit, UT Tooele, UT	1.0023

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
41660	San Angelo, TX Irion, TX Tom Green, TX	0.8914
41700	San Antonio, TX Bexar, TX Comal, TX Guadalupe, TX Wilson, TX Atascosa, TX Bandera, TX Kendall, TX Medina, TX	0.9428
41740	San Diego-Carlsbad-San Marcos, CA San Diego, CA	1.2104
41780	Sandusky, OH Erie, OH	0.9916
41884	San Francisco-San Mateo-Redwood City, CA Marin, CA San Francisco, CA San Mateo, CA	1.6166
41900	San Germán-Cabo Rojo, PR Lajas, PR Cabo Rojo, PR Sabana Grande, PR San Germán, PR	0.5618
41940	San Jose-Sunnyvale-Santa Clara, CA Santa Clara, CA San Benito, CA	1.6569

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
41980	San Juan-Caguas-Guaynabo, PR	0.5120
	Aguas Buenas, PR	
	Barceloneta, PR	
	Bayamón, PR	
	Canóvanas, PR	
	Carolina, PR	
	Cataño, PR	
	Comerio, PR	
	Corozal, PR	
	Dorado, PR	
	Florida, PR	
	Guaynabo, PR	
	Humacao, PR	
	Juncos, PR	
	Las Piedras, PR	
	Loiza, PR	
	Maguabo, PR	
	Manatí, PR	
	Morovis, PR	
	Naranjito, PR	
	Rio Grande, PR	
	San Juan, PR	
	Toa Alta, PR	
	Toa Baja, PR	
	Trujillo Alto, PR	
	Vega Alta, PR	
	Vega Baja, PR	
	Yabucoa, PR	
	Aibonito, PR	
	Barranquitas, PR	
	Ciales, PR	
	Maunabo, PR	
	Orocovs, PR	
	Quebradillas, PR	
	Arecibo, PR	
	Camuy, PR	
	Hatillo, PR	
	Caguas, PR	
	Cayey, PR	
	Cidra, PR	
	Gurabo, PR	
	San Lorenzo, PR	

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
42020	San Luis Obispo-Paso Robles, CA San Luis Obispo, CA	1.2364
42044	Santa Ana-Anaheim-Irvine, CA Orange, CA	1.2231
42060	Santa Barbara-Santa Maria, CA Santa Barbara, CA	1.1823
42100	Santa Cruz-Watsonville, CA Santa Cruz, CA	1.6478
42140	Santa Fe, NM Santa Fe, NM	1.1539
42220	Santa Rosa-Petaluma, CA Sonoma, CA	1.5419
42260	Sarasota-Bradenton-Venice, FL Manatee, FL Sarasota, FL	1.0520
42340	Savannah, GA Bryan, GA Chatham, GA Effingham, GA	0.9968
42540	Scranton--Wilkes-Barre, PA Lackawanna, PA Luzerne, PA Wyoming, PA	0.8898
42644	Seattle-Bellevue-Everett, WA King, WA Snohomish, WA	1.2189
42680	Sebastian-Vero Beach, FL Indian River, FL	1.0205
43100	Sheboygan, WI Sheboygan, WI	0.9622
43300	Sherman-Denison, TX Grayson, TX	0.9063
43340	Shreveport-Bossier City, LA Bossier, LA Caddo, LA De Soto, LA	0.9450

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
43580	Sioux City, IA-NE-SD Dixon, NE Dakota, NE Woodbury, IA Union, SD	0.9807
43620	Sioux Falls, SD Lincoln, SD Minnehaha, SD McCook, SD Turner, SD	1.0190
43780	South Bend-Mishawaka, IN-MI St. Joseph, IN Cass, MI	1.0492
43900	Spartanburg, SC Spartanburg, SC	0.9780
44060	Spokane, WA Spokane, WA	1.1137
44100	Springfield, IL Menard, IL Sangamon, IL	0.9477
44140	Springfield, MA Franklin, MA Hampden, MA Hampshire, MA	1.0744
44180	Springfield, MO Christian, MO Greene, MO Webster, MO Dallas, MO Polk, MO	0.9028
44220	Springfield, OH Clark, OH	0.9160
44300	State College, PA Centre, PA	0.9364
44700	Stockton, CA San Joaquin, CA	1.2197
44940	Sumter, SC Sumter, SC	0.8617

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
45060	Syracuse, NY Madison, NY Onondaga, NY Oswego, NY	1.0331
45104	Tacoma, WA Pierce, WA	1.1501
45220	Tallahassee, FL Gadsden, FL Leon, FL Wakulla, FL Jefferson, FL	0.9532
45300	Tampa-St. Petersburg-Clearwater, FL Hernando, FL Hillsborough, FL Pasco, FL Pinellas, FL	0.9748
45460	Terre Haute, IN Clay, IN Vermillion, IN Vigo, IN Sullivan, IN	0.9344
45500	Texarkana, TX-Texarkana, AR Bowie, TX Miller, AR	0.8639
45780	Toledo, OH Fulton, OH Lucas, OH Wood, OH Ottawa, OH	1.0219
45820	Topeka, KS Shawnee, KS Jackson, KS Jefferson, KS Osage, KS Wabaunsee, KS	0.9306
45940	Trenton-Ewing, NJ Mercer, NJ	1.1550
46060	Tucson, AZ Pima County, AZ	0.9810

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
46140	Tulsa, OK Creek, OK Osage, OK Rogers, OK Tulsa, OK Wagoner, OK Okmulgee, OK Pawnee, OK	0.8638
46220	Tuscaloosa, AL Tuscaloosa, AL Greene, AL Hale, AL	0.9106
46340	Tyler, TX Smith, TX	0.9393
46540	Utica-Rome, NY Herkimer, NY Oneida, NY	0.8950
46660	Valdosta, GA Brooks, GA Echols, GA Lanier, GA Lowndes, GA	0.8922
46700	Vallejo-Fairfield, CA Solano, CA	1.6136
47020	Victoria, TX Victoria, TX Calhoun, TX Goliad, TX	0.9125
47220	Vineland-Millville-Bridgeton, NJ Cumberland, NJ	1.0481

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
47260	Virginia Beach-Norfolk-Newport News, VA Chesapeake City, VA Currituck, NC Gloucester, VA Hampton City, VA Isle of Wight, VA James City, VA Mathews, VA Newport News City, VA Norfolk City, VA Poquoson, VA Portsmouth City, VA Suffolk City, VA Virginia Beach City, VA Williamsburg City, VA York, VA Surry, VA	0.9370
47300	Visalia-Porterville, CA Tulare, CA	1.0626
47380	Waco, TX McLennan, TX	0.9203
47580	Warner Robins, GA Houston, GA	0.8933
47644	Warren-Farmington-Hills-Troy, MI Lapeer, MI Macomb, MI Oakland, MI St. Clair, MI Livingston, MI	1.0718

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
47894	Washington-Arlington-Alexandria, DC-VA-MD-WV Alexandria City, VA Arlington, VA Calvert, MD Charles, MD Clarke, VA Fairfax, VA Fairfax City, VA Falls Church City, VA Fauquier, VA Fredericksburg City, VA Jefferson, WV Loudoun, VA Manassas City, VA Manassas Park city, VA Prince Georges, MD Prince William, VA Spotsylvania, VA Stafford, VA District of Columbia, DC Warren, VA	1.1784
47940	Waterloo-Cedar Falls, IA Black Hawk, IA Bremer, IA Grundy, IA	0.8963
48140	Wausau, WI Marathon, WI	1.0364
48260	Weirton-Steubenville, WV-OH Brooke, WV Hancock, WV Jefferson, OH	0.8595
48300	Wenatchee, WA Chelan, WA Douglas, WA	1.1029
48424	West Palm Beach-Boca Raton-Boynton FL Palm Beach, FL	1.0286
48540	Wheeling, WV-OH Belmont, OH Marshall, WV Ohio, WV	0.8000

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
48620	Wichita, KS Butler, KS Harvey, KS Sedgwick, KS Sumner, KS	0.9661
48660	Wichita Falls, TX Archer, TX Wichita, TX Clay, TX	0.8860
48700	Williamsport, PA Lycoming, PA	0.8676
48864	Wilmington, DE-MD-NJ Cecil, MD New Castle, DE Salem, NJ	1.1389
48900	Wilmington, NC Brunswick, NC New Hanover, NC Pender, NC	1.0484
49020	Winchester, VA-WV Frederick, VA Winchester City, VA Hampshire, WV	1.0757
49180	Winston-Salem, NC Davie, NC Forsyth, NC Stokes, NC Yadkin, NC	0.9888
49340	Worcester, MA Worcester, MA	1.1430
49420	Yakima, WA Yakima, WA	1.0497
49500	Yauco, PR Guánica, PR Guayanilla, PR Peñuelas, PR Yauco, PR	0.4432
49620	York-Hanover, PA York, PA	1.0017

CBSA Code	Urban Area (Constituent Counties or County Equivalents) [2]	Wage Index[1]
49660	Youngstown-Warren-Boardman, OH-PA Mahoning, OH Trumbull, OH Mercer, PA	0.9383
49700	Yuba City, CA Sutter, CA Yuba, CA	1.1438
49740	Yuma, AZ Yuma, AZ	0.9710

[1] Wage index values are based on FY 2003 hospital cost report data before reclassification. This wage index is further adjusted. Wage index values greater than 0.8 are subject to a budget neutrality adjustment. Wage index values below 0.8 are adjusted to be the greater of a 15-percent increase, subject to a maximum wage index value of 0.8, or a budget neutrality adjustment calculated by multiplying the hospital wage index value for a given area by the budget neutrality factor. We have completed all of these adjustments and included them in the wage index values reflected in this table.

[2] This column lists each CBSA area name and each county or county equivalent, in the CBSA area. Counties not listed in this Table are considered to be rural areas. Wage Index values for these areas are found in Table B.

TABLE B--HOSPICE WAGE INDEX FOR RURAL AREAS

CBSA Code Number	Nonurban Area	Wage Index[3]
1	Alabama	0.8092
2	Alaska	1.1365
3	Arizona	0.9496
4	Arkansas	0.8000
5	California	1.2210
6	Colorado	0.9941
7	Connecticut	1.2482
8	Delaware	1.0346
10	Florida	0.9161
11	Georgia	0.8094
12	Hawaii	1.1138
13	Idaho	0.8656
14	Illinois	0.8869
15	Indiana	0.9102
16	Iowa	0.9254
17	Kansas	0.8526
18	Kentucky	0.8281
19	Louisiana	0.8000
20	Maine	0.9000
21	Maryland	0.9515
22	Massachusetts[5]	1.2431
23	Michigan	0.9660
24	Minnesota	0.9757
25	Mississippi	0.8249
26	Missouri	0.8450
27	Montana	0.9157
28	Nebraska	0.9250
29	Nevada	0.9535
30	New Hampshire	1.1570
31	New Jersey[4]	--------
32	New Mexico	0.8882
33	New York	0.8776
34	North Carolina	0.9155
35	North Dakota	0.8000
36	Ohio	0.9230
37	Oklahoma	0.8133

CBSA Code Number	Nonurban Area	Wage Index[3]
38	Oregon	1.0397
39	Pennsylvania	0.8869
40	Puerto Rico[5]	0.4654
41	Rhode Island[4]	--------
42	South Carolina	0.9132
43	South Dakota	0.9040
44	Tennessee	0.8344
45	Texas	0.8491
46	Utah	0.8677
47	Vermont	1.0387
48	Virgin Islands	0.9026
49	Virginia	0.8464
50	Washington	1.0941
51	West Virginia	0.8109
52	Wisconsin	1.0184
53	Wyoming	0.9909
65	Guam	1.0246

[3] Wage index values are based on FY 2003 hospital cost report data before reclassification. This wage index is further adjusted. Wage index values greater than 0.8 are subject to a budget neutrality adjustment. Wage index values below 0.8 are adjusted to be the greater of a 15-percent increase, subject to a maximum wage index value of 0.8, or a budget neutrality adjustment calculated by multiplying the hospital wage index value for a given area by the budget neutrality factor. We have completed all of these adjustments and included them in the wage index values reflected in this table.

[4] All counties within the State are classified as urban.

[5] Based on CBSA designations Massachusetts and Puerto Rico have areas designated as rural. However, no IPPS hospitals are located in those rural area(s) for FY 2008. Because more recent data is not available for those areas, we are using the methodology described in this proposed rule.

[FR Doc. 07–2120 Filed 4–26–07; 4:00 pm]
BILLING CODE 4120–01–C

Federal Register

Tuesday,
May 1, 2007

Part VIII

The President

Proclamation 8133—Asian/Pacific American Heritage Month, 2007

Proclamation 8134—National Charter Schools Week, 2007

Federal Register
Vol. 72, No. 83
Tuesday, May 1, 2007

Presidential Documents

Title 3—

The President

Proclamation 8133 of April 26, 2007

Asian/Pacific American Heritage Month, 2007

By the President of the United States of America

A Proclamation

During Asian/Pacific American Heritage Month, we honor the many contributions citizens of Asian and Pacific Island ancestry have made to our great land.

The millions of Americans who trace their origins to nations in the Asian/Pacific region have enriched America. The entrepreneurship and innovation of Asian/Pacific Americans have strengthened our economy. Asian/Pacific Americans enrich our Nation with their strong values of love of family and community. Many Asian/Pacific Americans are serving the cause of freedom and peace around the world, and our Nation is grateful for their service. These good men and women defend our safety and contribute to the character and greatness of America.

To honor the achievements and contributions of Asian/Pacific Americans, the Congress, by Public Law 102–450, as amended, has designated the month of May each year as ''Asian/Pacific American Heritage Month.''

NOW, THEREFORE, I, GEORGE W. BUSH, President of the United States of America, do hereby proclaim May 2007 as Asian/Pacific American Heritage Month. I call upon the people of the United States to learn more about the history of Asian/Pacific Americans and their many contributions to our Nation and to observe this month with appropriate programs and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-sixth day of April, in the year of our Lord two thousand seven, and of the Independence of the United States of America the two hundred and thirty-first.

[FR Doc. 07–2169
Filed 4–30–07; 9:00 am]
BILLING CODE 3195–01–P

Presidential Documents

Proclamation 8134 of April 27, 2007

National Charter Schools Week, 2007

By the President of the United States of America

A Proclamation

Across our country, charter schools are providing quality education for America's students. During National Charter Schools Week, we recognize the important contributions of charter schools and underscore our commitment to ensuring that all children receive the education they need to lead lives of purpose and success.

Charter schools are public schools that provide families with a valuable educational alternative. Because they are not bound by many regulatory requirements, charter schools have the flexibility to innovate in ways that will best meet students' academic needs. Today, there are about 4,000 charter schools in 40 States and the District of Columbia helping more than one million students realize their full potential.

My Administration is dedicated to providing parents with more choices so that their children will have the best opportunity to gain the skills necessary to compete and succeed in the global economy. Through the No Child Left Behind Act, we are setting high standards, expanding parents' options, and closing the achievement gap. Charter schools are getting results and helping guide children across the country on the path to a better life.

This week we thank educational entrepreneurs for supporting charter schools, and we honor all those involved in charter schools for helping their students reach high expectations.

NOW, THEREFORE, I, GEORGE W. BUSH, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim April 29 through May 5, 2007, as National Charter Schools Week. I applaud our Nation's charter schools and all those who make them a success, and I call on parents of charter school students to share their success stories and help Americans understand more about the important work of charter schools.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-seventh day of April, in the year of our Lord two thousand seven, and of the Independence of the United States of America the two hundred and thirty-first.

[FR Doc. 07–2170
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Billing code 3195–01–P

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REMINDERS

The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

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